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(54) **REAL TIME BRACHYTHERAPY SPATIAL REGISTRATION AND VISUALIZATION SYSTEM**

RÄUMLICHE BRACHYTHERAPIE REGISTRIERUNG UND VISUALISIERUNG IN ECHTZEIT

SYSTEME D'ENREGISTREMENT ET DE VISUALISATION SPATIAL EN TEMPS REEL UTILISE EN
CURIETHERAPIE

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(73) Proprietor: **Computerized Medical Systems, Inc.**
St. Louis, MO 63132 (US)

(72) Inventors:
• **BURDETTE, Everette, C.**
Champaign, IL 61821 (US)
• **KOMADINA, Bruce, M.**
Urbana, IL 61801 (US)

(74) Representative: **Lawrence, John**
Barker Brettell,
138 Hagley Road,
Edgbaston
Birmingham B16 9PW (GB)

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Description

[0001] This invention is a continuation-in-part of U.S. Serial Application No. 08/977,362, filed on November 24, 1997.

[0002] The present invention is directed in general to an improved method and apparatus for carrying out minimally invasive treatments of the human body by virtual reality visualization of the treatment area. More particularly the invention is concerned with use of an apparatus and method for providing real time images of a human anatomy undergoing treatment along with rapid radiation seed therapy planning and rapid performance of therapy including an automatic seed loading methodology which enhances therapeutic treatment with greatly improved efficiency both in terms of time and resources.

[0003] New minimally invasive surgical procedures are most often optically guided, but such optical guidance methods do not permit visualization and guidance of instruments or probes within (inside) the target tissue or organ. Incorporation of real-time three-dimensional visualization inside diseased tissues would provide accurate guidance of therapy. Open-magnet MRI is used to visualize some procedures such as thermal therapy and brain biopsies. However, the method is expensive, not truly real-time, and is limited in application.

[0004] Numerous conventional treatment methods involve attempts to provide a targeted dosage of radiation or chemicals to the organ, and such treatments are often based on general anatomical assumptions of size and location. These methods suffer from inaccuracy of localizing the target for any one particular individual and potential real time changes of relative orientation and position of target tissue, normal tissue, and radiation therapy devices.

[0005] It is instructive in explaining the invention to consider one specific type of exemplary condition, adenocarcinoma of the male prostate which is the most commonly diagnosed cancer in the male population of the United States. At present, 254,000 new cases of prostate cancer were diagnosed in 1995 and 317,000 in 1996. In the 1960s, a method of implanting radioactive gold or iodine seeds was developed. With this approach, the radioactive material is permanently placed into the prostate via a retropubic approach during laparotomy when diagnostic lymphadenectomy was also being performed. A high dose of radiation is delivered to the prostate as the radioactive seeds decay. In several reports, the five year disease free survival ("local control") obtained by this method was compared to similarly staged patients treated with an external radiation beam. In view of this, gold was replaced by ¹²⁵I implantation for safety of personnel doing implantation. Except for early stage prostate cancer (T2a tumors), inferior rates of local control are reported with "free hand" ¹²⁵I-iodine implantation. There was significant dose inhomogeneity due to the nonuniformity of seed placement, leading to underdosing of portions of the prostate gland and significant complications due to

overdosing of adjacent healthy tissue structures. The poor results for local control and normal tissue complication were attributed to the doctor's inability to visualize and hence control where the radioactive seeds were actually being deposited inside the patient.

[0006] Recently, transrectal ultrasonography ("TRUS") has been used to visualize ¹²⁵I-iodine seed placement during transperineal implantation. The early reported rates of serious late complications is higher than external beam therapy. Even with this technique, significant imprecisions in seed placement are observed. Due to the proximity of the prostate to the rectum and bladder, incorrect seed placement may lead to serious overdosing of these structures and late complications.

[0007] The recent transrectal ultrasound guided transperineal implant technique has been developed which is in use. That procedure is described in three steps: (1) the initial volumetric assessment of the prostate gland performed using ultrasound, (2) development of a radiation therapy "pre-plan," and (3) performing the actual intraoperative implant. The purpose of the initial volumetric assessment prior to the pre-plan or implantation is to obtain a quantitative understanding of the size of the prostate, which is then used to determine the total activity and distribution of radioactivity which is to be implanted into the prostate. To perform the assessment, an ultrasound probe is physically attached to a template. The template is a plastic rectangle which contains an array of holes separated at predefined intervals, usually 5 mm. The template system serves two purposes: (1) to fix the ultrasound probe, and hence the imaging plane to the reference frame of the catheter and seed positions, and (2) to guide the catheters into the prostate volume. More specifically, the template system serves as a reference frame for spatial quantities which are required for the description of the implant procedure. Using transrectal ultrasound, a number of serial ultrasound images are obtained at 5-mm intervals, and the prostate is outlined on each image. The images are taken so that the entire prostate gland is covered. This results in a stack of two-dimensional outlines, or contours, which, taken together, outline the entire three-dimensional prostate volume. From this volume, the quantitative volume of the prostate is calculated.

[0008] Once the three-dimensional contour data has been obtained for the prostate volume, a radiation therapy plan which describes the positions of the radioactive seeds within the prostate is developed. This plan attempts to optimize the dose to the prostate, minimize the dose to surrounding healthy tissue, and minimize dose inhomogeneity. The positions of the radioactive seeds are constrained to fall within the catheter tracks, since the seeds are placed within the prostate transperineally via these catheters. The result of the pre-plan describes the positions and strengths of the radioactive seeds within the catheter which optimizes the dose to the prostate.

[0009] Intraoperatively, the TRUS probe is inserted, and the template is mounted against the perineum. As

previously described, the template is a plastic rectangle which contains an array of holes separated at fixed intervals. These holes act as guides for the catheters. The TRUS probe is inserted into the rectum and placed so that the image corresponds to the prostate base (the maximum depth). Two or three catheters are inserted into the tissue surrounding the prostate or in the periphery of the prostate to immobilize the gland. These catheters contain no radioactive seeds. This image serves as a spatial reference for all further images and seed positions within the prostate. Subsequently, catheters are inserted into the gland based on the pre-plan through the template. The ultrasound probe is positioned each time so that the catheter, and hence seeds, which are inserted into the prostate are visible on the ultrasound image. If the placement of the catheter within the prostate is not according to the pre-plan, the catheter is then withdrawn and reinserted until the catheter is correctly placed. This is a time-consuming process; and it is very difficult to achieve optimal placement. Invariably, the catheters deflect angularly as they are inserted, and their positions are difficult to determine by two-dimensional ultrasound. This is due to the fact that the visualization process is a two-dimensional process while the actual implant procedure is three-dimensional. Once all the seeds are in place, another series of two-dimensional images are obtained to quantify the final, resultant dose distribution delivered to the patient. In some instances, a pair of orthogonal fluoroscopic images are also obtained to determine the final seed placements. This procedure is usually performed a few weeks post implant.

[0010] A device according to the preamble of claim 1 is known from US-A-5 242 373.

[0011] These above described prior art systems suffer from inherent inaccuracy, the inability to correct the positioning of the radioactive seeds without repeated withdrawal and reinsertion of seeds into the prostate and are not real time manipulations of the therapeutic medium. Further, the overall positioning of the template and patient may be different during treatment compared to the assessment phase. Consequently, the catheter position and seed position may be at an undesired position relative to the presumed assessment phase location.

[0012] An aspect of the invention provides a system for radiation seed treatment of the body of a patient including a device to establish a therapy plan for treatment of an organ of the patient, a radioactive seed container for holding at least one radioactive seed and an insertion device for insertion of the radioactive seed in position into the patient, the improvement characterized by a sensor positioned to monitor loading of the radioactive seed from the radioactive seed container into the insertion device for a determination whether the loading is in accordance with the therapy plan, and a display for displaying a status based at least in part on the determination.

[0013] It is therefore an object of the invention to provide an improved system for invasive treatment of the human body.

[0014] An embodiment of the invention provides a novel system for real time and/or near real time, three-dimensional visualization of a human organ undergoing invasive treatment.

[0015] An embodiment of the present invention provides a more precise and accurate implant placement for radiation therapy, thermal therapy, and surgical ablation.

[0016] An embodiment of the invention provides an improved system for generating a three-dimensional image data set of a human organ for a treatment protocol using a real-time ultrasound imaging system with spatial landmarks to relate the image data set to present time, invasive treatment devices.

[0017] An embodiment of the invention to provide a novel system for spatial registration of two-dimensional and three-dimensional images of a human organ, such as the human prostate, with the actual location of the organ in the body.

[0018] An embodiment of the invention provides an improved system for three-dimensional virtual imaging of the male prostate gland and overlaid virtual imaging of devices being inserted into the prostate for deposition of radioactive seeds for cancer therapy.

[0019] An embodiment of the invention to provide an automated and system for loading of radioactive therapeutic treatment seeds based on a clinical plan enabling rapid treatment based on substantially real time pre-planning using rapid patient organ evaluation.

[0020] These and other embodiments and advantages of the invention will be readily apparent from the following description of the preferred embodiments thereof, taken in conjunction with the accompanying drawings described below.

Brief Description of the Drawings

[0021]

FIGURE 1A illustrates a block diagram of an embodiment of the invention and **Figure 1B** shows an alternate embodiment for a three-dimensional probe;

FIGURE 2 illustrates an ultrasound guided implant system;

FIGURE 3A illustrates patient setup for a radioactive implant procedure; **FIGURE 3B** illustrates an anatomical prostate phantom used for testing and planning; and **FIGURE 3C** illustrates in detail a probe holder/stepper assembly shown partly in **Figure 3A**.

FIGURE 4A illustrates a front schematic view of a brachytherapy phantom; and **FIGURE 4B** illustrates a side schematic view of the brachy-therapy phantom.

FIGURE 5A illustrates reconstruction of standard or-

thogonal image planes from a three-dimensional image stack; and **FIGURE 5B** the reconstruction of oblique image plants from a three-dimensional image stack;

FIGURE 6 illustrates the viewing geometry for a three-dimensional translucent reconstruction of an image;

FIGURE 7A illustrates translucent images of a human prostate for four different viewing angles; and **FIGURE 7B** illustrates translucent images of a phantom organ for six different viewing angles;

FIGURE 8 illustrates a time sequenced image of the prostate organ in Figure 7A showing approach of a catheter containing a radioactive seed, deposition of the seed and withdrawal of the catheter leaving the seed;

FIG. 9 illustrates isodose distributions of radiation from a single radioactive seed;

FIG. 10 illustrates a flow chart of software routine for processing imaging data for visualization;

FIG. 11 illustrates a virtual reality head mounted display;

FIG. 13A illustrates a perspective view of a stepper assembly with the probe in position and FIG. 13B illustrates a perspective view of the probe stepper along with a probe stabilization system; and

FIG. 14 illustrates a redundant monitoring and automatic loading system for radioactive seeds and inert spacers.

Detailed Description of Preferred Embodiments

[0022] A system 10 constructed in accordance with an example of the invention is illustrated generally in FIG. 1. A three-dimensional probe 12 accumulates image data from a treatment region or organ of a patient, image data is processed using a three-dimensional imaging card 14. The probe 12 preferably is an ultrasound device but can be any other rapid imaging technology, such as rapid CT or MR. A conventional personal computer 16 having a monitor can be used to operate on the image data from the imaging card 14 using conventional software and hardware tools to be described in more detail hereinafter. Radioactive seeds 18 are provided for insertion using any one of a variety of conventional means for inserting devices or articles into the human body, such as insertion devices 19, which may be either needles or stiff catheters. The three-dimensional ultrasound probe 12, therefore, provides an image signal to the computer 16 and a virtual realty interface card 13 coupled to the imaging card 14

which enables a user to visualize a translucent image of the patient organ and real time interaction of any one of a variety of treatment devices, such as the implant needles 19 or a Foley catheter 20, and one of the seeds 18 within the organ. Computer software can be utilized in a conventional manner to visualize the three-dimensional imaging data in various formats (see Appendix and discussion hereinafter). The formats include orthogonal two dimensional images, oblique two-dimensional images, and translucent three-dimensional rendering. All of these reconstructions can be directly displayed on the computer monitor; and three-dimensional translucent, stereoscopic, rendering is also available in the VR (Virtual Reality) mode.

[0023] One of the preferred ultrasound probe 12 for example, is a conventional Kretz ultrasound imaging system manufactured by Kretz Corporation, now available as Medison Combison 530 through Medison America Corporation, Pleasantown, CA. This system and other such conventional systems are readily available and can provide real time ultrasound image data. The Medison Combison ultrasound system incorporates an endorectal probe which acquires multiple image planes in real time and in certain embodiments the software (see Appendix) reconstructs the translucent three-dimensional volume. Another example is of a B&K Leopard ultrasound imaging system with endorectal imaging probe (Boston, MA). Alternate systems include biplanar two-dimensional imaging systems with the probe mounted in a stepper motor driven holder for rapid automatic acquisition of multiple image planes.

[0024] In a most preferred form of the invention, the system 10 includes computer software for real-time image acquisition, image contouring, dose calculation and display software, dose volume histograms, three-dimensional dose contours, post-implant seed localization, and the patient scheduling spreadsheet software.

[0025] The system software enables a two-dimensional and three-dimensional image visualization for brachytherapy employing two-dimensional ultrasound imaging for use in radioactive seed implants of the prostate. The software for the brachytherapy seed implant and dose calculation system was developed on a Pentium-based processor with supporting graphics and digitizing hardware. The software consists of two-dimensional and three-dimensional routines. The two-dimensional tools consist of standard imaging tools largely available for CT and MRI applications. These tools include displays of the imaging volume in any of the three standard orthogonal planes (transverse, sagittal, and coronal), in addition to the ability to display the imaging in any arbitrary, oblique imaging plane. Standard image processing tools such as real time window leveling, zoom and pan will be available. The three-dimensional tools consist of a three-dimensional rendering of the actual contour slices imaging data. Based upon volumetric patient studies, the prostate volume can be displayed. The user has the option of viewing one or a mixture of two-dimensional and three-dimen-

sional surface views on the monitor.

[0026] Contouring tools are also available for the user to draw with the mouse outlines, or contours, of any structure visible on the imaging plane. Each contour can be varied as to color, line thickness, and line pattern to aid in distinguishing between different contour sets.

[0027] Once a set of two-dimensional contours has been defined, either manually or automatically, on a number of different image slices they can be reconstructed in real time in the three-dimensional translucent view (described in more detail hereinafter). This results in a surface rendering of the volume bounded by the contours. The surface rendering can be chosen to be transparent, solid, or invisible (not rendered at all).

[0028] Once a seed has been placed into treatment position (details concerning seed implantation provided later), the user has the ability to display the dose of one or a set of seeds. The dose as a function of position for a cylindrical ¹²⁵ or ¹⁰³ Pd seed of a given activity can be determined from a lookup table or calculated from an analytic formula. The dose field can be visualized as a set of isodose lines in two-dimensions or isodose surface in three-dimensions. The process of constructing an isodose line or surface is defined by simply drawing a point for each pixel/voxel which contains a certain specified dose value. For example, the user can specify that the 137 Gy, 120 Gy, 100 Gy, and 60 Gy isodose lines be drawn on the two-dimensional slice for each image plane, and the 137 Gy isodose surface shown on the three-dimensional rendered mode. Again, similar to the contoured volumes, the isodose surface can be reconstructed in any of the user selected modes defined for contoured volumes.

[0029] The features/capabilities of the system software functionalities include: complete patient database archive and dose plan "playback"; external image import capability; look-up tables for multiple seed kits and template guides; multiple ultrasound imaging machine configuration capability; image slice contouring using mouse, with edit capability; image cropping, image sizing, tiling, cascading; three-dimensional display of prostate, urethra, and other anatomies; rapid "on-line" dose calculation in operating room/cysto suite during procedure; dose display with isodose lines, three-dimensional translucent, and dithered isodoses; image export and printing (dose slices, contour slices, etc.); seed implant plan export and printing; dose volume histograms (with export and printing); three-dimensional image support including three-dimensional image reconstruction from slices; three-dimensional display of isodose surfaces; image slice selection from three-dimensional image through any transverse plane; post-implant assessment including automatic seed localization; computer-controlled stepper; selection of manual (mouse entry), semi-automatic (button push), or full automatic (computer-controlled stepper) ultrasound image collection.

[0030] For collecting ultrasound image data, the diagnostic transrectal ultrasound probe 12 (see FIG. 2) is

inserted into the patient's rectum to obtain real time volumetric images of the prostate for use during the implant procedure. The diagnostic probe 12 is preferably a phased array probe designed so that the array of transducers can rotate about the axis of the array sweeping out a three-dimensional imaging volume. As the probe 12 rotates, images are captured and digitized by use of the imaging card 14 (see FIG. 1), so as to create a fixed number of images slices per rotation. An alternative method utilizes a transverse oriented phased array form of the endorectal probe 12 which is moved longitudinally in an automated rapid sequence so as to create a series of transverse image slices automatically. Another embodiment of the probe 12 can incorporate multiple transverse phased arrays (shown in phantom in FIG. 1B) arranged parallel to each other orthogonal to the axis of an endorectal probe to produce multiple simultaneous image slices (see, for example, FIGS. 5A and 5B). The three-dimensional image data will be represented as a three dimensional image raster.

[0031] The ultrasound probe 12 can be mounted into a probe holder 30 (see FIGS. 3A and 3C) with FIG. 3B illustrating one example of an ultrasound image from an anatomical prostate phantom employed to carry out testing and planning. The probe holder 30 includes a digital encoder 42 for providing information regarding the position of all of the desired ultrasound image planes in the prostate relative to each other. The image plane location will be automatically sent to the system computer and "tagged" to the acquired ultrasound image for that position (FIG. 2). Thus, it will be possible to reproduce the longitudinal and lateral positions of the implant catheters for the ultrasound therapy applicators and for the temperature probes.

[0032] A probe holder/stepper assembly 21 (see FIG. 1A and in particular FIG. 13) accommodates most ultrasound endorectal probes from various manufacturers. A "collett" 23 surrounds the probe 12 and is inserted into the stepper / probe holder assembly 21. The stepper 21 is a digital device with an automatic imaging link to the ultrasound machine and to the remainder of the system 10. The stepper 21 has three digitally encoded axes: main probe stage longitudinal axis 31, needle insertion template longitudinal axis 33, and the rotational axis 35 of the imaging probe itself. The stepper 21 automatically records the longitudinal (z-axis) position and sends that information to the computer 16. Whenever the user desires to acquire an image plane, the spatial position of that image plane is automatically registered with that image. Thus, it requires less than a minute to digitally acquire and document all the image planes in a typical volume study. The stepper 21 can be incrementally moved by the user with stepper knob 34 and the template 25 can be stepped by template positioning control 37.

[0033] The holder/stepper assembly 21 can move the probe 12 in 2.5 mm increments. A transrectal probe from B&K was used which operates at a frequency of 7.5 MHz and contains two sets of 128 transducer elements form-

ing both transverse and sagittal imaging assays. The imaging probe 12 was moved via a knob on the side of the stepper 21 and its position measured via a digitally interfaced optical position encoder. The probe holder/stepper 21 with transrectal probe 12 mounted is shown in FIG. 1. The real time multi-plane ultrasound probe 12 was modeled by obtaining single digitized transverse images at either 2.5 or 5 mm intervals through the ultrasound prostate imaging phantom. The ultrasound prostate phantom is available from Computerized Imaging Reference Systems Inc. and contains a model of a prostate, urethra, and seminal vesicles immersed in a gel filled plastic box. The box has a cylindrical hole in the base for the insertion and positioning of the transrectal probe and a perineal membrane for performing practice brachytherapy implants. FIGS. 4A and 4B display a schematic of the brachytherapy phantom. Once the static image slices have been digitized they were then inputted to the software in a continuous cycle to model actual real time acquisition of a full volume. Multiple sets of image slices can be obtained and randomly cycled to more accurately simulate the actual three-dimensional real time ultrasound probe 12. The image slices are input to the software transparently.

[0034] A probe stabilization system 27 (see FIG. 13B) is designed for use with any standard probe holder/stepper 21, yet it is optimized for use as part of the system 10. This stabilization system 27 attaches easily and quickly to the cysto or operating room table using clamps 28, yet provides maximum flexibility during patient setup. The stabilization system 27 provides for five degrees of freedom of motion, yet is robust and stable. The probe stabilization system 27 includes a stepper probe stand control 28 which allows up and down movement. Further motion control is provided by stabilizer control 29 which enables up and down motion and left to right along rods 30 (horizontal) and rods 31 (vertical). Gross motions are positively controlled in a stable manner. Fine motions are obtained with the same controls and are exactly reproducible.

[0035] A variety of the templates 25 (see FIG. 1) for the needles 19 can be used with the system 10. All of these implant templates are disposable preferably. The system 10 can also accommodate use of other standard templates 25. The system software (see Appendix) can store the configuration of any number of the templates 25 for immediate recall. Each template 25 stored in the system 10 is spatially registered with each ultrasound system configuration stored in the system software.

[0036] The system templates 25 provide assurance of sterility for patient contact at a cost similar to that of sterilization of the usual standard templates. The disposable system templates 25 are a fraction of the cost of standard reusable templates and provide greater safety.

[0037] There are several possible image processing cards which could be utilized; however, using current modalities each of the processing cards is configured specifically for three-dimensional. The three-dimensional im-

age raster is buffered; and thus, for example, if the two-dimensional images are 512x512 and there are sixteen image planes in the probe 12, and each pixel is a byte (256 gray scales), at least a $512 \times 512 \times 16$ byte = 4.2 Mbyte image buffer in the card 14 is needed. Several commercial cards (for example, made by Coreco, Matrox and Integral Technologies) can be equipped with this amount of video RAM (VRAM), but the way the card's hardware interacts with the computer's video and software drivers does not utilize this data in three-dimensional. Current available methodologies enable augmenting the software and some hardware of these cards so that they can act as a three-dimensional card. The processing and memory architecture preferably is designed to allow for simultaneous image acquisition and processing. The digitizing card should also preferably have standard imaging tools, such as real time window and leveling, zoom and pan of the ultrasound images. Some existing cards (e.g., Matrox; Coreco) do provide standard imaging tools.

[0038] The three-dimensional image data arising from the ultrasound probe 12 is preferably buffered on the imaging card 14. The three-dimensional image is preferably represented as a series of two-dimensional images. This is referred to as the image stack or three-dimensional image raster. The three-dimensional image raster is represented in memory as a linear array of bytes of length $N \times M \times P$ where N is the width of the two-dimensional image in pixels, M is the height a two-dimensional image in pixels, and P is the number of two-dimensional images in the image stack.

[0039] In a preferred embodiment the user can include defined formats. Entire three-dimensional image stacks at specific times during the intraoperative session can be stored in the DICOM standard. The user will have the ability to select a three-dimensional image volume for archiving as part of the system software. These image stacks can then be reviewed in any of the various visualization modes (standard orthogonal two-dimensional views, oblique two-dimensional views, or three-dimensional translucent views) as described above. In addition, the user will have the ability to store any of the two-dimensional views available at any time during the intraoperative session.

[0040] The computational platform can, for example, be any form of computing means, such as the personal computer 16, which incorporates a PCI bus architecture. Currently, PCI bus is preferable over the ISA or EISA bus because the PCI bus is much faster. However, a generic system which will be suitable for this applicable will be described. A 200 MHz (or greater speed) Pentium/Pentium-Pro computer supplied with 128 Mbytes of RAM and a 6.0 Gbyte hard disk should be sufficient RAM and disk memory to run the software in a real-time fashion and to archive all patient data. There should be sufficient RAM to facilitate host image processing in parallel with on-board image processing for quality assurance checks. A high resolution monitor capable of displaying at least 1280x1024x64 bit resolutions is preferably used.

[0041] Based on currently available technology, the ultrasound images obtained from the ultrasound imaging system of the ultrasound probe 12 can be of good diagnostic quality. When transforming this input image data into a three-dimensional representation, whether in the three-dimensional perspective mode or the real time VR mode, the resultant volumes can, however, be noisy and hinder diagnostic and spatial accuracy. In order to improve the image quality, a number of conventional hardware and software filters can be used which will filter the incoming image data stored on the imaging card 14. Routines such as image pixel averaging, smoothing, and interpolation can improve the three-dimensional rendering of the imaging volume. These sets of filters or routines are to be distinguished from the set of standard imaging tools running on the host CPU which are available within a conventional imaging software package.

[0042] In the preferred embodiment, three of the perspective views are the standard transverse, coronal and sagittal two-dimensional views. These three orthogonal views are taken from a user specified location within the imaging space. For example, the user can request that the three orthogonal views have their common centers at a spatial position of (5.0 cm, 15.0, 25.0 cm) relative to the origin of the template system. One also can select the reference point of either of the three orthogonal views independently, that is the three views do not have to have common center points. As mentioned hereinbefore, FIGS. 5A and 5B show examples of several example two-dimensional views from a three-dimensional ultrasound image volume. FIG. 6 shows a number of possible viewing directions, and FIG. 7 gives further examples of translucent three-dimensional viewing from different angles. The three-dimensional ultrasound image volume was obtained from actual ultrasound images of a human prostate and of a prostate implant phantom.

[0043] On each of the views, one can define, draw and edit contours using conventional computer software, such as Microsoft Foundation Class (MFC) view files. Each contour can be given a unique name by the user, and then drawn by the user using the mouse of the computer 16. All attributes of the contours such as name and color can, based on conventional imaging software, be user selectable. The user can also edit the contours by selecting functions, such as adding a point to a contour, deleting a point from a contour or deleting the entire contour. Once the contours are defined, the user has the option to render them in three-dimensional or view in conventional two-dimensional mode on the three-dimensional perspective mode or viewed in the VR mode. Again, all contour three-dimensional attributes such as color, lighting, and shading are user controlled. The contours by default appear on the two-dimensional images, however, the user can control the individual contour's two-dimensional and three-dimensional visibility.

[0044] In order to improve the ability to visualize the real time, three-dimensional information, the three-dimensional image raster can be rendered as a real time,

transparent, three-dimensional volume. This transparent volume can be viewed and displayed on the monitor of the computer 16 at any arbitrary viewing angle and is calculated using conventional three-dimensional object reconstruction algorithms.

Such standard algorithms can render a large imaging volume in fractions of a second, even on present day computing platforms. The transparent nature of the reconstruction thus allows the user to "see" inside any objects which appear in the imaging volume. For example, if the prostate is imaged in the imaging volume, then it will be reconstructed as a transparent volume, in which other anatomical landmarks such as the urethra, tissue abnormalities or calcifications can be seen. In addition, if any other objects such as needles or catheters are inserted into the prostate, and if they are visible in the ultrasound images, they will be seen as they enter the prostate (see FIG. 8 showing introduction of the seed 18 with the catheter/needle 19). Since the volumes are rendered as transparent solids, the needles 19 (and other articles) can thus easily be seen as they move inside the prostate volume as well. Since the ultrasound images are obtained in real time, the three-dimensional perspective reconstruction is also rendered in real time. The preferred algorithm for the perspective three-dimensional reconstruction is the known Bresenham ray-trace algorithm.

[0045] As described above, in the routine process of brachytherapy planning, the patient undergoes an initial volumetric ultrasound scan using the probe 12. This scan is done before the radiation therapy planning or the actual implant. During the radiation therapy planning, the ideal positions of the radioactive seeds 18 (see FIG. 1) within the prostate are determined. This ideal seed distribution is optimized to deliver a dose distribution within the prostate that will deliver all the radiation dose to the target volume only, while sparing the surrounding healthy tissues such as the rectum and bladder. The optimal positions of the seeds 18 and the optimal position of the needles 19 are recorded for later use in the operating room when the needles 19 are loaded into the patient. The seeds 18 are then loaded into the needles 19, and the physician then attempts to place the needles 19 inside the prostate using a template 25 according to the treatment dose plan positions (again, see example in FIG. 8).

[0046] In the most preferred embodiment the seeds 18 are loaded through the needles 19. A selection of different types of the seeds 18 (different levels of radioactivity) can be loaded through passageways, P, shown in FIG. 14. Optical sensors 90 and 91 are redundantly disposed adjacent each of the passageways P with an associated microprocessor 93 and 97 monitoring the number of the seeds 18 being instilled through the needle 19. Radiation sensors 96 and 98 monitor the radiation activity of the seeds 18 being loaded into the needle 19. Spacers 100 are also instilled into the needle 19 for separating the seeds 18 to achieve the desired level of radiation activity and radiation contours. Optical sensors 92 sense, redundantly as for the seeds 18, the passage of the spacers

100.

[0047] In a most preferred form of the invention, an automatic seed/needle loading method is implemented automatically loading implant needles 19 with the radiation seeds 18 and spacers 29 based upon a pre-plan (dose plan) determined in the operating room (OR). This method accommodates the spacers 29 and separate leaded-acrylic see-through "bins" for the seeds 18 of two different activity levels. Thus, the needles 19 can be auto-loaded based upon optimal dose plans requiring seeds of different activity levels. The automatic seed/needle loading method and system interfaces directly to the computer 16 and reads the dose plan information using the software of the Appendix. A display on the auto-loader then displays to the operator each needle number, template coordinate location, and status of needle loading. Each of the needles 19 are attached one at a time to the auto-loader assembly with a standard luer lock. The auto-loader has a sensor at the needle attachment point which detects if the needle 19 is attached for loading. Each of the needles 19 are then loaded in accordance with the pre-plan.

[0048] The automatic seed/needle loading method and system is therefore completely double-redundant, as mentioned hereinbefore. It incorporates the use of two totally independent microprocessors 93 and 94 which constantly check each other. Both the microprocessors 93 and 94 are also in communication with the system computer 16. The seeds 18 and the spacers 29 are optically counted independently. Needle loading is optically checked for total number of loaded items and, further, a radiation detector array scans each needles 19 to confirm that the seed/spacer loading radiation pattern matches the pre-plan. This automatic method and system will do so in the operating room in minimal time, without the risk of human error in the loading of needles. The seed loading method will include a pair of redundant 8051 microcontrollers (the microprocessors 93 and 94) which will be interfaced to the dose-planning and implant system computer 16 via a serial port. This interface will read the dose pre-plan information from the computer 16, without the need for paper printouts and manual loading. That information will be transferred to a controller which controls the loading of each needle 19. The requirements and design criteria for the automatic seed-needle loading method and system are described as follows: self-contained and capable of loading seeds and spacers; system will protect operator of system from radiation; dual redundant counting of seeds and spacers; dual redundant radiation detectors for measuring radiation from active seeds versus spacers; dual redundant measurement of radiation seed positions in needles; system check for failure of either or both redundant counting and measurement systems; alarm to both operator and to dose-planning and implant computer system in the event of error; ongoing account of seed and spacer inventory; tracks needle loading configuration and displays to operator the designated template grid hole coordinates for each needle

loaded; sterilized cassettes for holding seeds and spacers, plus sterilizable needle connector; includes one cassette for seeds and one cassette for spacers; dispenses one seed and one spacer at a time, and verifies optically and by radiation detector; system displays needle number and template grid location during loading procedure; automatic acquisition of needle loading plan from main system computer; serial interface with handshake protocol and verification; self-contained (mechanical, power, logic, microcontrollers); operates only if connected to main system computer.

[0049] A convenient storage system for the needles 18 can be loaded by the automatic seed/needle loading method system. The face of this unit has a hole grid pattern which matches the implant template 25. Loaded needles may be inserted into this unit until they are used. The entire unit is shielded for radiation leakage minimization. The template-like face of the unit is available in both a reusable, sterilizable version and disposable versions which match all standard implant template faces. Faces of the unit detach easily and quickly for sterilization or disposal.

[0050] The dose as a function of position for a cylindrical ^{125}I seed of a given activity can be determined from a lookup table or calculated from a conventional analytic formula. The dose field can be visualized as a set of isodose lines in two-dimensional or isodose surface in three-dimensional. The dose computation routine is based upon the TG43 standard adopted by the AAPM (American Association of Physicists in Medicine) entitled "Dosimetry of Interstitial Brachytherapy Sources": Recommendations of the AAPM Radiation Therapy Committee Task Group No. 43 which specifies the dose model and the data used in the dose calculation. This particular implementation runs extremely fast on a conventional 233MHz PC, computing the dose for a single seed in less than 0.5 seconds. The total three-dimensional dose distribution within the prostate for a 100 seed implant requires only 50 seconds, or less than one minute total computation time. Thus, this can be done "on line" in the operating room.

[0051] In the two-dimensional, three-dimensional perspective, or the real time VR modes, the user has the ability to view the optimized seeds 18 and the needles 19 in the same volume as the real time ultrasound data. This allows the physician to see exactly where the needles 19 should go and hence make adjustments to position the needles 19 optimally. The pre-planned, optimal positioned needles 19 and the seeds 18 can be rendered again as a transparent solid, the color of which is user selectable. As the real needles 19 are inserted into the prostate, their positions relative to the ideal needle placements based on the dose plan can be monitored in real time. Any deviation of the position of a given needles 19 can be quickly and accurately readjusted so as to follow the path of the ideal needles 19. As the different needles 19 are placed at different positions inside the prostate, the viewing angle can be adjusted to facilitate viewing of

the needle or catheter placement. FIGS. 5A and 5B displays perspective three-dimensional views and the three orthogonal reconstructions of the image data along with the pre-planned catheter positions. The pre-planned needles 19 can also be viewed in the VR mode as virtual objects overlaid onto the imaging volume.

[0052] A flowchart description of the translucent volume visualization methodology is shown in FIG. 10. The input image volume is described by the vectors i, j, k of appropriate magnitude for the volume. The viewing angle parameters are the angles θ, ϕ described on FIG. 6 and FIG. 10. The rotation matrix, R , is calculated using the formulae given in the flowchart of FIG. 10. The entire imaging volume is calculated by multiplying the rotation matrices in the x, y, z directions by the respective vectors i, j and k describing the incremental portions along the x, y, z directions. Thus, the multiplying vector is $(i-i_o, j-j_o, k-k_o)$ where i_o, j_o, k_o are the starting points along x, y and z axes and the volume is determined by summing the component contributions shown in FIG. 10. The three-dimensional translucent image is then created by computing the translucent two-dimensional image over the entire image volume and summing the z -pixels.

[0053] A virtual reality interface system can be composed of a conventional head mounted display (HMD) 50 shown in FIG. 11 and a 6D (x, y, z , roll, pitch, yaw) tracking system. The HMD 50 consists of two color monitors which mount to a head set in the position directly in front of the eyes. The HMD 50 is based on the principal that whatever is displayed on each monitor is directly incident on the retina for each eye, and hence true three-dimensional images can be created by rendering objects as three-dimensional perspective images for each eye. Given the distance between the eyes (the interocular distance which is approximately 80 mm) and the distance and spherical angles of the distance of the center line between the eyes from the coordinate origin, the two-dimensional images which appear in each of the two monitors can be determined exactly as described above. This results in a true three-dimensional image as perceived by the user. Therefore, as the user moves his or her head or moves around the room, the distance from the origin and the spherical angles also change. This motion of the user or user's head can be obtained from the VR tracking system. Given these spatial parameters, the images which are reconstructed in the two eye monitors can be updated in real time, giving the user the illusion of the object really existing in three-dimensional space. The user literally has the ability to walk around the object, viewing it in three-dimensional space.

[0054] Instead of reconstructing computer generated geometric objects as is usually the case in VR, the transparent, three-dimensional reconstruction of the real time imaging data will preferably be reconstructed. Hence as the physician walks around the patient undergoing the implant, the physician will see the three-dimensional ultrasound volume mapped inside the patient's pelvis, spatially correlated to the position of the patient's real pros-

tate (or other organ) and anatomy. The physician can "see" inside the patient to the extent of what is visible in the ultrasound imaging volume. Since the ultrasound probe 12 is locked down to the template, which is then secured to the floor, the exact positions of all voxels in the ultrasound imaging volume are known exactly relative to the template, and hence relative to the room.

[0055] As the needles 19 are inserted into the patient, they will appear in the image volume and hence are reconstructed in the VR reconstruction. All of this occurs in real time so that the physician also can see the needles 19 enter the prostate in real time. As mentioned above, if the pre-planned, optimized needles 19 are displayed, the physician can then see the position of the actual needles 19 as they are being inserted relative to the optimal placement. Hence, the physician has the ability to adjust the needles 19 to correspond to their optimal positions. In addition, since the needles 19 are automatically extracted, the computer software has the ability to calculate and render the three-dimensional dose distribution in real time as the needles 19 are being inserted.

[0056] As an example, a currently available, a fast and inexpensive HMD is made by Virtual-IO Corporation (Mountain View, CA). The HMD is full color with two 0.70 LCD displays with a resolution of 180,000 pixels per LCD panel. The video input is NTSC with field sequential format. The LCD panels are semitransparent, allowing the real outside world to be included in the virtual reconstruction. The field of view is 30° for each eye. A six degree of freedom (6 DOF) tracking system can also be attached to the HMD. The 6 DOF tracking system allows for the determination of the spatial position of the user's head and the yaw, pitch, and roll of the head. The conventional head set weighs only 8 ounces and comes with stereo sound. Stereo sound is an extremely valuable technology in the operating room. With this capability, the physician has the ability to monitor the patient's heart rate and respiration rate while performing the implant. Hence any fluctuation in the patient's vital signs can be instantly accessed and acted thereon if necessary.

[0057] The radioactive seeds 18 are made of high density material such as stainless steel, and hence have a very bright response in the ultrasound images. Therefore, automatic seed detection in the ultrasound images can readily be accomplished, for example, by a simple thresholding algorithm along with the requirement that the resultant objects which are removed by threshold have a certain maximum size determined by the actual size of the seeds.

[0058] Near-real-time visualization will provide immediate feedback to the physician during the implant process itself. There is a clear need for the visualization being available during the implant process. The nearly real time visualization is of great importance to the effective use of a translucent overlay of the ideal seed pre-plan (from the therapy planning process) in the three-dimensional volume. The physician can "see" in nearly real time the relationship of the needles and seeds being implanted

to the ideal pre-plan locations and quickly accommodate redirection required prior to leaving the radiation seeds. Further, the need for this in three-dimensional representation is very important to overcome the greatest fundamental limitation in brachytherapy, which is knowing at the same time both the lateral placement and longitudinal placement of needles and seeds relative to the target volume and pre-plan. This is a three-dimensional problem which has up until now been addressed in two-dimensional in a stepwise fashion without the ability to "see" the exact location of where you are in the target. This real time three-dimensional visualization also would speed the implant process in the case of brachytherapy as well as make it more accurate. It would also speed other minimally invasive surgical procedures and localized tissue ablation procedures (for example, cryosurgery or localized selected ablation of diseased liver tissue or local removal of breast tissue). These procedures could be accomplished with real time visualization inside the tissue being treated with greater accuracy in shorter time. This aspect would reduce operating room time and costs to the patient and health care system.

[0059] While preferred embodiments of the inventions have been shown and described, it will be clear to those skilled in the art that various changes and modifications can be made without departing from the invention in its broader aspects as set forth in the claims provided hereinafter.

Claims

1. A system for radiation seed (18) treatment of the body of a patient including a device for establishing a radiation dose plan for treatment of an organ of the patient, a radioactive seed cassette for holding at least one radioactive seed and an insertion device (19) for insertion of the radioactive seed in position into the patient, **characterized by** a sensor (90, 91, 96, 98) positioned to monitor loading of the radioactive seed from the radioactive seed container into the insertion device for determining whether the loading is in accordance with the radiation dose plan, and a display for displaying a status based at least in part on the determination.

2. The system as defined in Claim 1 further including:

an image display system (12) for displaying a treatment region of the patient's body based on real-time or near real-time image data corresponding to the treatment region, the treatment region including the organ, and a computer system (16) for providing a translucent three-dimensional volume image by the image display system of the treatment region and at least one of a translucent or opaque image of the actual insertion device (19), a translucent or

opaque image of an optimally-positioned insertion device (19) according to the radiation dose plan, a translucent or opaque image of an optimally-positioned radioactive seed (18) according to the radiation dose plan, and a translucent or opaque image of the actual radioactive seed.

3. The system as defined in Claim 1 or Claim 2 wherein the radioactive seed (18) includes a radioactive seed for permanent implantation into the body of the patient.
4. The system as defined in any preceding claim wherein the sensor (90, 91, 96, 98) includes at least one of a radiation sensor (96, 98) and an optical sensor (90, 91) positioned to monitor loading of the radioactive seed into the insertion device.
5. The system as defined in any preceding claim wherein a plurality of radioactive seeds are loaded into the insertion device, and wherein the insertion device further contains at least one spacer (100) between at least two of the radioactive seeds.
6. The system as defined in any preceding claim wherein each of the radioactive seeds (18) comprises a source of at least one selectable level of radioactivity.
7. The system as defined in any one of Claims 1 to 4 wherein the at least one radioactive seed (18) comprises a plurality of different radioactive seeds.
8. The system as defined in any preceding claim wherein at least two sensors (90, 91, 96, 98) are redundantly disposed adjacent one entry passageway of the insertion device (19).
9. The system as defined in Claim 4 or any claim dependant directly or indirectly from claim 4, further including a microprocessor (93, 94) coupled to said sensor (90, 91, 96, 98) and programmed to receive input from the sensor about the loading of the radioactive seed into the insertion device and determine, at least partially on the basis of that input, whether the loading is in accordance with the radiation dose plan.
10. The system as defined in claim 5 or any claim directly or indirectly dependant from Claim 5 further including a microprocessor (93, 94) coupled to the sensor and programmed to receive input from the sensor about the loading of at least one of the spacers and the radioactive seed into the insertion device and determine, at least partially on the basis of that input, whether the loading is in accordance with the radiation dose plan.
11. The system as defined in claim 5 or any claim directly

or indirectly dependant from Claim 5 further including a container for holding a plurality of the spacers (100).

12. The system as defined in Claim 11 further including at least two radioactive seed containers, each radioactive seed container for holding at least one radioactive seed of a different radioactivity level than that held by each other radioactive seed container. 5
13. The system as defined in any preceding claim wherein the status display is configured to display to an operator an identifier of the radiation seed container and the insertion device and a status of loading the radioactive seed and the spacers into the insertion device. 10 15
14. The system as defined in Claim 5 or any claim dependant directly or indirectly from Claim 5 further including a system computer (16) having radiation dose plan information which can be downloaded into a programmed microprocessor (93, 94) for use by the automatic loader to automatically load the radioactive seed and the spacers into the insertion device. 20 25
15. The system as defined in any preceding claim further including a template (25) disposed outside the patient and which has openings for receiving the insertion device (19) and the template comprises a disposable material for a single use. 30
16. The system as defined in claim 2 or any claim dependant directly or indirectly from claim 2 wherein the image display system is an ultrasound imaging system (12), and wherein the ultrasound imaging system is coupled to a computer (16) programmed to detect an image of said radioactive seed using a threshold ultrasound signal analysis program. 35 40
17. The system as defined in Claim 2 or any claim dependant directly or indirectly from claim 2 wherein the insertion device (19) is spatially registered relative to the treatment region, the organ of the patient and the radioactive seed. 45
18. The system as defined in Claim 2 or any claim dependant directly or indirectly from Claim 2 wherein the computer system (16) is configured to provide a translucent three-dimensional volume image by the image display system of the treatment region, a translucent or opaque image of the actual insertion device, and a translucent or opaque image of an optimally-positioned insertion device according to the radiation dose plan. 50 55
19. The system as defined in Claim 2 or any claim dependant directly or indirectly from Claim 2 wherein

the computer system (16) is configured to provide a translucent three-dimensional volume image by the image display system of the treatment region, a translucent or opaque image of the actual radioactive seed, and a translucent or opaque image of an optimally-positioned radioactive seed according to the radiation dose plan.

20. The system as defined in Claim 2 or any claim dependant directly or indirectly from Claim 2 wherein the computer system (16) is configured to provide a translucent three-dimensional volume image by the image display system of the treatment region and at least two of a translucent or opaque image of the actual insertion device, a translucent or opaque image of an optimally-positioned insertion device according to the radiation dose plan, a translucent or opaque image of an optimally-positioned radioactive seed according to the radiation dose plan, and a translucent or opaque image of the actual radioactive seed.
21. The system as defined in Claim 2 or any claim dependant directly or indirectly from Claim 2 wherein the computer system (16) is configured to provide a translucent three-dimensional volume image by the image display system of the treatment region, a translucent or opaque image of the actual insertion device, a translucent or opaque image of an optimally-positioned insertion device according to the radiation dose plan, a translucent or opaque image of an optimally-positioned radioactive seed according to the therapy plan, and a translucent or opaque image of the actual radioactive seed.
22. The system as defined in Claim 4 or any claim dependant directly or indirectly from Claim 4 wherein the sensor (96, 98) includes both a radiation sensor and an optical sensor (90, 91), each being positioned to monitor loading of the radioactive seed from the radioactive seed container into the insertion device.
23. The system as defined in claim 10 or any claim directly or indirectly dependant from Claim 10 wherein the microprocessor (93, 94) is programmed to receive input about the loading of both the spacers (100) and the radioactive seed (16) into the insertion device (19).
24. The system as defined in Claim 9 or any claim dependant directly or indirectly from Claim 9, further including redundant microprocessors (93, 94) coupled to said sensor (90, 91, 96, 98), each redundant microprocessor being programmed to receive input from the sensor about the loading of the radioactive seed into the insertion device and determine, at least partially on the basis of that input, whether the loading is in accordance with the radiation dose plan.

25. The system as defined in Claim 2 or any claim dependant directly or indirectly from Claim 2 wherein the image display system is configured to display a treatment region of the patient's body based on real-time image data corresponding to the treatment region. 5
26. The system as defined in Claim 2 or any claim dependant directly or indirectly from Claim 2 wherein the image display system is configured to display a treatment region of the patient's body based on near real-time image data corresponding to the treatment region. 10
27. The system as defined in Claim 1 or any claim dependant directly or indirectly from Claim 1 further comprising an automatic loader configured to automatically load the radioactive seed from the radioactive seed container into insertion device based on the radiation dose plan. 15 20
28. The system as defined in Claim 1 or any claim dependant directly or indirectly from Claim 1 wherein the organ is the patient's prostate. 25

Patentansprüche

1. Ein System zur Behandlung mit Bestrahlungsseed ("radiation seed") (18) des Körpers eines Patienten, wobei das System einschließt: 30
- a) eine Vorrichtung für die Etablierung eines Bestrahlungsdosisplans für die Behandlung eines Organs des Patienten, 35
 - b) eine radioaktiv Seed-Kassette zum Halten mindestens eines radioaktiven Seeds und
 - c) eine Insertionsvorrichtung (19) für die Insertion des radioaktiven Seeds in Position in dem Patienten, **gekennzeichnet durch** 40
 - d) einen Sensor (90, 91, 96, 98), der positioniert ist, so dass er das Beladen des radioaktiven Seeds aus dem radioaktiv Seed-Behälter in die Insertionsvorrichtung aufzeichnet und bestimmt, ob das Beladen in Übereinstimmung mit dem Bestrahlungsdosisplan ist, und 45
 - e) eine Anzeige zum Anzeigen eines Status, der mindestens zum Teil auf der Bestimmung basiert. 50
2. Das System nach Anspruch 1, wobei das System ferner einschließt:
- ein Bildanzeigesystem (12) zum Anzeigen einer Behandlungsregion des Patientenkörpers, das auf Echtzeit oder nahe Echtzeit Bilddaten basiert, die zu der Behandlungsregion korrespondieren, wobei die Behandlungsregion das Or-

gan einschließt und ein Computersystem (16), das ein lichtdurchlässiges dreidimensionales Volumenbild durch das Bildanzeigesystem der Behandlungsregion und mindestens eines von einem lichtdurchlässigen oder opaken Bild der tatsächlichen Insertionsvorrichtung (19), einem lichtdurchlässigen oder opaken Bild einer optimal positionierten Insertionsvorrichtung (19) gemäß des Bestrahlungsdosisplans, einem lichtdurchlässigen oder opaken Bild eines optimal positionierten radioaktiven Seeds (18) gemäß des Bestrahlungsdosisplans und einem lichtdurchlässigen oder opaken Bild des tatsächlichen radioaktiven Seeds zur Verfügung stellt.

3. Das System nach Anspruch 1 oder Anspruch 2, wobei das radioaktive Seed (18) ein radioaktives Seed für eine dauerhafte Implantation in den Körper des Patienten einschließt.
4. Das System nach einem der vorhergehenden Ansprüche, wobei der Sensor (90, 91, 96, 98) mindestens eines von einem Bestrahlungssensor (96, 98) und einem optischen Sensor (90, 91), so positioniert, so dass er das Beladen des radioaktiven Seeds in die Insertionsvorrichtung aufzeichnet, einschließt.
5. Das System nach einem der vorhergehenden Ansprüche, wobei die Insertionsvorrichtung mit einer Vielzahl von radioaktiven Seeds beladen wird, und wobei die Insertionsvorrichtung ferner mindestens ein Zwischenstück (100) zwischen mindestens zwei der radioaktiven Seeds enthält.
6. Das System nach einem der vorhergehenden Ansprüche, wobei jedes der radioaktiven Seeds (18) eine Strahlungsquelle mindestens eines auswählbaren Levels an Radioaktivität einschließt.
7. Das System nach einem der Ansprüche 1 bis 4, wobei das mindestens eine radioaktive Seed (18) eine Vielzahl von verschiedenen radioaktiven Seeds einschließt.
8. Das System nach einem der vorhergehenden Ansprüche, wobei mindestens zwei Sensoren (90, 91, 96, 98) redundant angrenzend zu einer Eingangspassage der Insertionsvorrichtung (19) angebracht sind.
9. Das System nach Anspruch 4 oder einem der direkt oder indirekt von Anspruch 4 abhängigen Ansprüche, das ferner einen Mikroprozessor (93, 94) gekoppelt an den Sensor (90, 91, 96, 98) einschließt und programmiert ist, so dass er Input von dem Sensor über das Beladen des radioaktiven Seeds in die Insertionsvorrichtung erhält und mindestens teilweise

se auf der Basis des Inputs bestimmt, ob das Beladen in Übereinstimmung mit dem Bestrahlungsdosisplan ist.

10. Das System nach Anspruch 5 oder einem der direkt oder indirekt von Anspruch 5 abhängigen Ansprüche, das ferner einen Mikroprozessor (93, 94) gekoppelt an den Sensor einschließt und programmiert ist, so dass er Input von dem Sensor über das Beladen mindestens eines der Zwischenstücke und des radioaktiven Seeds in die Insertionsvorrichtung erhält und mindestens teilweise auf der Basis dieses Inputs bestimmt, ob das Beladen in Übereinstimmung mit dem Bestrahlungsdosisplan ist. 5
11. Das System nach Anspruch 5 oder einem der direkt oder indirekt von Anspruch 5 abhängigen Ansprüche, das ferner einen Behälter zum Halten einer Vielzahl von Zwischenstücken (100) einschließt. 10
12. Das System nach Anspruch 11, das ferner mindestens zwei radioaktive Seedbehälter einschließt, wobei jeder radioaktive Seedbehälter zum Halten mindestens eines radioaktiven Seeds eines Radioaktivitätslevels, das verschieden ist zu dem Level, das von jedem anderen radioaktiven Seedbehälter gehalten wird. 15
13. Das System nach einem der vorhergehenden Ansprüche, wobei die Statusanzeige konfiguriert ist, so dass sie einem Benutzer einen Identifikator des Bestrahlungsseedbehälters und der Insertionsvorrichtung und ein Status des Beladens des radioaktiven Seeds und der Zwischenstücke in die Insertionsvorrichtung anzeigt. 20
14. Das System nach Anspruch 5 oder einem der direkt oder indirekt von Anspruch 5 abhängigen Ansprüche, das ferner ein Computersystem (16) einschließt, das Bestrahlungsdosisplan Informationen besitzt, welche in einen programmierten Mikroprozessor (93, 94) zur Verwendung durch den automatischen Belader heruntergeladen werden können, so dass die Insertionsvorrichtung automatisch mit dem radioaktiven Seed und den Zwischenstücke beladen wird. 25
15. Das System nach einem der vorhergehenden Ansprüche, das ferner eine Matrice (25) einschließt, die außerhalb des Patienten angebracht ist, und die Öffnungen zum Empfang der Insertionsvorrichtung (19) hat, und die Matrice schließt ein Wegwerfmateri- 30
16. Das System nach Anspruch 2 oder einem der direkt oder indirekt von Anspruch 2 abhängigen Ansprüche, wobei das Bildanzeigesystem ein Ultraschallsystem (12) ist, und wobei das Ultraschallsystem 35

an einen Computer (16) gekoppelt ist, der programmiert ist, so dass ein Bild des radioaktiven Seeds unter Verwendung eines Grenzwert-Ultraschallsignalanalyseprogramms nachgewiesen wird.

17. Das System nach Anspruch 2 oder einem der direkt oder indirekt von Anspruch 2 abhängigen Ansprüche, wobei die Insertionsvorrichtung (19) räumlich registriert relativ zu der Behandlungsregion, dem Organ des Patienten und dem radioaktiven Seed ist. 40
18. Das System nach Anspruch 2 oder einem der direkt oder indirekt von Anspruch 2 abhängigen Ansprüche, wobei das Computersystem (16) konfiguriert ist, so dass es ein lichtdurchlässiges dreidimensionales Volumenbild durch das Bildanzeigesystem der Behandlungsregion, ein lichtdurchlässiges oder opakes Bild der tatsächlichen Insertionsvorrichtung, und ein lichtdurchlässiges oder opakes Bild einer optimal positionierten Insertionsvorrichtung gemäß des Bestrahlungsdosisplans zur Verfügung stellt. 45
19. Das System nach Anspruch 2 oder einem der direkt oder indirekt von Anspruch 2 abhängigen Ansprüche, wobei das Computersystem (16) konfiguriert ist, so dass es ein lichtdurchlässiges dreidimensionales Volumenbild durch das Bildanzeigesystem der Behandlungsregion, ein lichtdurchlässiges oder opakes Bild des tatsächlichen radioaktiven Seeds, und ein lichtdurchlässiges oder opakes Bild eines optimal positionierten radioaktiven Seeds gemäß des Bestrahlungsdosisplans zur Verfügung stellt. 50
20. Das System nach Anspruch 2 oder einem der direkt oder indirekt von Anspruch 2 abhängigen Ansprüche, wobei das Computersystem (16) konfiguriert ist, so dass es ein lichtdurchlässiges dreidimensionales Volumenbild durch das Bildanzeigesystem der Behandlungsregion und mindestens zwei von einem lichtdurchlässigen oder opaken Bild einer tatsächlichen Insertionsvorrichtung, einem lichtdurchlässigen oder opaken Bild einer optimal positionierten Insertionsvorrichtung gemäß des Bestrahlungsdosisplans, einem lichtdurchlässigen oder opaken Bild eines optimal positionierten radioaktiven Seeds gemäß des Bestrahlungsdosisplans, und einem lichtdurchlässigen oder opaken Bild des tatsächlichen radioaktiven Seeds zur Verfügung stellt. 55
21. Das System nach Anspruch 2 oder einem der direkt oder indirekt von Anspruch 2 abhängigen Ansprüche, wobei das Computersystem (16) konfiguriert ist, so dass es ein lichtdurchlässiges dreidimensionales Volumenbild durch das Bildanzeigesystem der Behandlungsregion, ein lichtdurchlässiges oder opakes Bild der tatsächlichen Insertionsvorrichtung, ein lichtdurchlässiges oder opakes Bild einer optimal positionierten Insertionsvorrichtung gemäß des Be-

strahlungsdosisplans, ein lichtdurchlässiges oder opakes Bild eines optimal positionierten radioaktiven Seeds gemäß des Therapieplans und ein lichtdurchlässiges oder opakes Bild des tatsächlichen radioaktiven Seeds zur Verfügung stellt.

22. Das System nach Anspruch 4 oder einem der direkt oder indirekt von Anspruch 4 abhängigen Ansprüche, wobei der Sensor (96, 98) sowohl einen Bestrahlungssensor, als auch einen optischen Sensor (90, 91) einschließt, wobei jeder positioniert ist, so dass er das Beladen des radioaktiven Seeds aus dem radioaktiven Seedbehälter in die Insertionsvorrichtung aufzeichnet. 10
23. Das System nach Anspruch 10 oder einem der direkt oder indirekt von Anspruch 10 abhängigen Ansprüche, wobei der Mikroprozessor (93, 94) programmiert ist, so dass er Input über das Beladen sowohl der Zwischenstücke (100), als auch des radioaktiven Seeds (18) in die Insertionsvorrichtung (19) erhält. 20
24. Das System nach Anspruch 9 oder einem der direkt oder indirekt von Anspruch 9 abhängigen Ansprüche, das ferner redundante Mikroprozessoren (93, 94) gekoppelt an den Sensor (90, 91, 96, 98) einschließt, wobei jeder redundante Mikroprozessor programmiert ist, so dass er Input von dem Sensor über das Beladen des radioaktiven Seeds in die Insertionsvorrichtung erhält und mindestens teilweise auf der Basis des Inputs bestimmt, ob das Beladen in Übereinstimmung mit dem Bestrahlungsdosisplan ist. 25 30
25. Das System nach Anspruch 2 oder einem der direkt oder indirekt von Anspruch 2 abhängigen Ansprüche, wobei das Bildanzeigesystem konfiguriert ist, so dass es eine Behandlungsregion des Patientenkörpers basierend auf Echtzeit Bilddaten korrespondierend zu der Behandlungsregion anzeigt. 35 40
26. Das System nach Anspruch 2 oder einem der direkt oder indirekt von Anspruch 2 abhängigen Ansprüche, wobei das Bildanzeigesystem konfiguriert ist, so dass es eine Behandlungsregion des Patientenkörpers basierend auf nahe Echtzeit Bilddaten korrespondierend zu der Behandlungsregion anzeigt. 45
27. Das System nach Anspruch 1 oder einem der direkt oder indirekt von Anspruch 1 abhängigen Ansprüche, das ferner einen automatischen Belader einschließt, der konfiguriert ist, so dass er, basierend auf den Bestrahlungsdosisplan, die Insertionsvorrichtung automatisch mit dem radioaktiven Seed aus dem radioaktiven Seedbehälter belädt. 50 55
28. Das System nach Anspruch 1 oder einem der direkt oder indirekt von Anspruch 1 abhängigen Ansprüche,

che, wobei das Organ die Prostata des Patienten ist.

Revendications

1. Système de traitement par grains radioactifs (18) d'un corps d'un patient comprenant un dispositif pour établir un plan de dosage des radiations pour le traitement d'un organe d'un patient, une cassette de grains radioactifs pour contenir au moins un grain radioactif, et un dispositif d'insertion (19) pour l'insertion du grain radioactif, en position, dans le patient, **caractérisé par** un capteur (90, 91, 96, 98) positionné pour surveiller le chargement du grain radioactif depuis le conteneur du grain radioactif dans le dispositif d'insertion afin de déterminer si ce chargement est conforme au plan de dosage des radiations, et un écran pour afficher un état basé au moins sur une partie de la détermination.
2. Système comme défini dans la revendication 1, comprenant en outre :
 - un système d'affichage d'images (12) pour afficher une région de traitement du corps du patient d'après des données d'image en temps réel ou quasi temps réel correspondant à la région de traitement, la région de traitement comprenant l'organe, et
 - un système informatique (16) pour fournir une image volumique tridimensionnelle translucide, à partir du système d'affichage d'images, de la région de traitement, et au moins une d'une image translucide ou opaque du dispositif d'insertion réel (19), une image translucide ou opaque d'un dispositif d'insertion (19) positionné de façon optimale selon le plan de dosage des radiations, une image translucide ou opaque d'un grain radioactif (18) positionné de façon optimale selon le plan de dosage des radiations, et une image translucide ou opaque du grain radioactif réel.
3. Système comme défini dans la revendication 1 ou 2 dans lequel le grain radioactif (18) comprend un grain radioactif pour implantation permanente dans le corps d'un patient.
4. Système comme défini dans une quelconque des revendications précédentes dans lequel le capteur (90, 91, 96, 98) comprend au moins un d'un capteur de radiations (96, 98) et d'un capteur optique (90, 91) positionnés pour surveiller le chargement du grain radioactif dans le dispositif d'insertion.
5. Système comme défini dans une quelconque des revendications précédentes dans lequel une pluralité de grains radioactifs sont chargés dans le dispo-

sitif d'insertion, et dans lequel le dispositif d'insertion contient en outre un espaceur (100) entre au moins deux des grains radioactifs.

6. Système comme défini dans une quelconque des revendications précédentes dans lequel chacun des grains radioactifs (18) comprend une source d'au moins un niveau sélectionnable de radioactivité. 5
7. Système comme défini dans l'une quelconque des revendications 1 à 4 dans lequel le au moins un grain radioactif (18) comprend une pluralité de grains radioactifs différents. 10
8. Système comme défini dans une quelconque des revendications précédentes dans lequel au moins deux capteurs (90, 91, 96, 98) sont disposés de façon redondante dans une position adjacente à un passage d'entrée du dispositif d'insertion (19). 15
9. Système comme défini dans la revendication 4 ou dans une quelconque revendication subordonnée directement ou indirectement à la revendication 4, comprenant en outre un microprocesseur (93, 94) couplé audit capteur (90, 91, 96, 98) et programmé pour recevoir une entrée depuis ce capteur au sujet du chargement du grain radioactif dans le dispositif d'insertion et déterminer, au moins partiellement, d'après cette entrée, si le chargement est conforme au plan de dosage des radiations. 20 25 30
10. Système comme défini dans la revendication 5, ou dans une quelconque revendication subordonnée directement ou indirectement à la revendication 5, comprenant en outre un microprocesseur (93, 94) couplé au capteur et programmé pour recevoir une entrée depuis ce capteur au sujet du chargement d'au moins un des espaceurs et du grain radioactif dans le dispositif d'insertion, et déterminer, au moins partiellement, d'après cette entrée, si le chargement est conforme au plan de dosage des radiations. 35 40
11. Système comme défini dans la revendication 5, ou dans une quelconque revendication subordonnée directement ou indirectement à la revendication 5, comprenant en outre un conteneur pour contenir une pluralité des espaceurs (100). 45
12. Système comme défini dans la revendication 11, comprenant en outre au moins deux conteneurs de grains radioactifs, chaque conteneur de grains radioactifs étant destiné à contenir au moins un grain radioactif d'un niveau de radioactivité différent de celui contenu par chaque autre conteneur de grains radioactifs. 50
13. Système comme défini dans l'une quelconque des revendications précédentes dans lequel l'affichage

d'état est configuré pour afficher à un opérateur un identificateur du conteneur de grains radioactifs et le dispositif d'insertion, et un état de chargement du grain radioactif et des espaceurs dans le dispositif d'insertion.

14. Système comme défini dans la revendication 5, ou dans une quelconque revendication subordonnée directement ou indirectement à la revendication 5, comprenant en outre un système informatique (16) ayant des informations de plan de dosage des radiations qui peuvent être téléchargées dans un microprocesseur programmé (93, 94) à utiliser par le chargeur automatique pour charger automatiquement le grain radioactif et les espaceurs dans le dispositif d'insertion.
15. Système comme défini dans l'une quelconque des revendications précédentes comprenant en outre une forme de référence (25) disposée à l'extérieur du patient et qui comporte des ouvertures pour recevoir le dispositif d'insertion (19), et cette forme de référence comprenant un matériau jetable destiné à une seule utilisation.
16. Système comme défini dans la revendication 2, ou dans une quelconque revendication subordonnée directement ou indirectement à la revendication 2, dans lequel le système d'affichage d'images est un système d'imagerie ultrasonique (12), et dans lequel le système d'imagerie ultrasonique est couplé à un ordinateur (16) programmé pour détecter une image dudit grain radioactif en utilisant un programme d'analyse de signal ultrasonique de seuil.
17. Système comme défini dans la revendication 2, ou dans une quelconque revendication subordonnée directement ou indirectement à la revendication 2, dans lequel le dispositif d'insertion (19) est enregistré dans l'espace par rapport à une région de traitement, à l'organe du patient et au grain radioactif.
18. Système comme défini dans la revendication 2, ou dans une quelconque revendication subordonnée directement ou indirectement à la revendication 2, dans lequel le système informatique (16) est configuré pour fournir une image volumique tridimensionnelle translucide depuis le système d'affichage d'image de la région de traitement, une image translucide ou opaque du dispositif d'insertion réel, et une image translucide ou opaque d'un dispositif d'insertion positionné de façon optimale selon le plan de dosage des radiations.
19. Système comme défini dans la revendication 2, ou dans une quelconque revendication subordonnée directement ou indirectement à la revendication 2, dans lequel le système informatique (16) est confi-

guré pour fournir une image volumique tridimensionnelle translucide depuis le système d'affichage d'images de la région de traitement, une image translucide ou opaque du grain radioactif réel, et une image translucide ou opaque d'un grain radioactif positionné de façon optimale selon le plan de dosage des radiations.

20. Système comme défini dans la revendication 2, ou dans une quelconque revendication subordonnée directement ou indirectement à la revendication 2, dans lequel le système informatique (16) est configuré pour fournir une image volumique tridimensionnelle translucide depuis le système d'affichage d'images de la région de traitement et d'au moins deux parmi une image translucide ou opaque du dispositif d'insertion réel, d'une image translucide ou opaque d'un dispositif d'insertion positionné de façon optimale selon le plan de dosage des radiations, d'une image translucide ou opaque d'un grain radioactif positionné de façon optimale selon le plan de dosage des radiations, et d'une image translucide ou opaque du grain radioactif réel.

21. Système comme défini dans la revendication 2, ou dans une quelconque revendication subordonnée directement ou indirectement à la revendication 2, dans lequel le système informatique (16) est configuré pour fournir une image volumique tridimensionnelle translucide depuis le système d'affichage d'images de la région de traitement, une image translucide ou opaque du dispositif d'insertion réel, une image translucide ou opaque d'un dispositif d'insertion positionné de façon optimale selon le plan de dosage des radiations, une image translucide ou opaque d'un grain radioactif positionné de façon optimale selon le plan de thérapie, et une image translucide ou opaque du grain radioactif réel.

22. Système comme défini dans la revendication 4, ou dans une quelconque revendication subordonnée directement ou indirectement à la revendication 4, dans lequel le capteur (96, 98) comprend à la fois un capteur de radiation et un capteur optique (90, 91), chacun étant positionné pour surveiller le chargement du grain radioactif depuis le conteneur de grain radioactif dans le dispositif d'insertion.

23. Système comme défini dans la revendication 10, ou dans une quelconque revendication subordonnée directement ou indirectement à la revendication 10, dans lequel le microprocesseur (93, 94) est programmé pour recevoir une entrée au sujet du chargement à la fois des espaceurs (100) et du grain radioactif (16) dans le dispositif d'insertion (19).

24. Système comme défini dans la revendication 9, ou dans une quelconque revendication subordonnée

directement ou indirectement à la revendication 9, comprenant en outre des microprocesseurs redondants (93, 94) couplés audit capteur (90, 91, 96, 98), chaque microprocesseur redondant étant programmé pour recevoir une entrée du capteur au sujet du chargement du grain radioactif dans le dispositif d'insertion, et pour déterminer, au moins partiellement d'après cette entrée, si le chargement est conforme au plan de dosage des radiations.

25. Système comme défini dans la revendication 2, ou dans une quelconque revendication subordonnée directement ou indirectement à la revendication 2, dans lequel le système d'affichage d'images est configuré pour afficher une région de traitement du corps du patient d'après des données d'image en temps réel correspondant à cette région de traitement.

26. Système comme défini dans la revendication 2, ou dans une quelconque revendication subordonnée directement ou indirectement à la revendication 2, dans lequel le système d'affichage d'images est configuré pour afficher une région de traitement du corps du patient d'après des données d'images en quasi temps réel correspondant à cette région de traitement.

27. Système comme défini dans la revendication 1, ou dans une quelconque revendication subordonnée directement ou indirectement à la revendication 1, comprenant en outre un chargeur automatique configuré pour charger automatiquement le grain radioactif depuis le conteneur de grains radioactifs dans le dispositif d'insertion d'après le plan de dosage des radiations.

28. Système comme défini dans la revendication 1, ou dans une quelconque revendication subordonnée directement ou indirectement à la revendication 1, dans lequel l'organe est la prostate d'un patient.

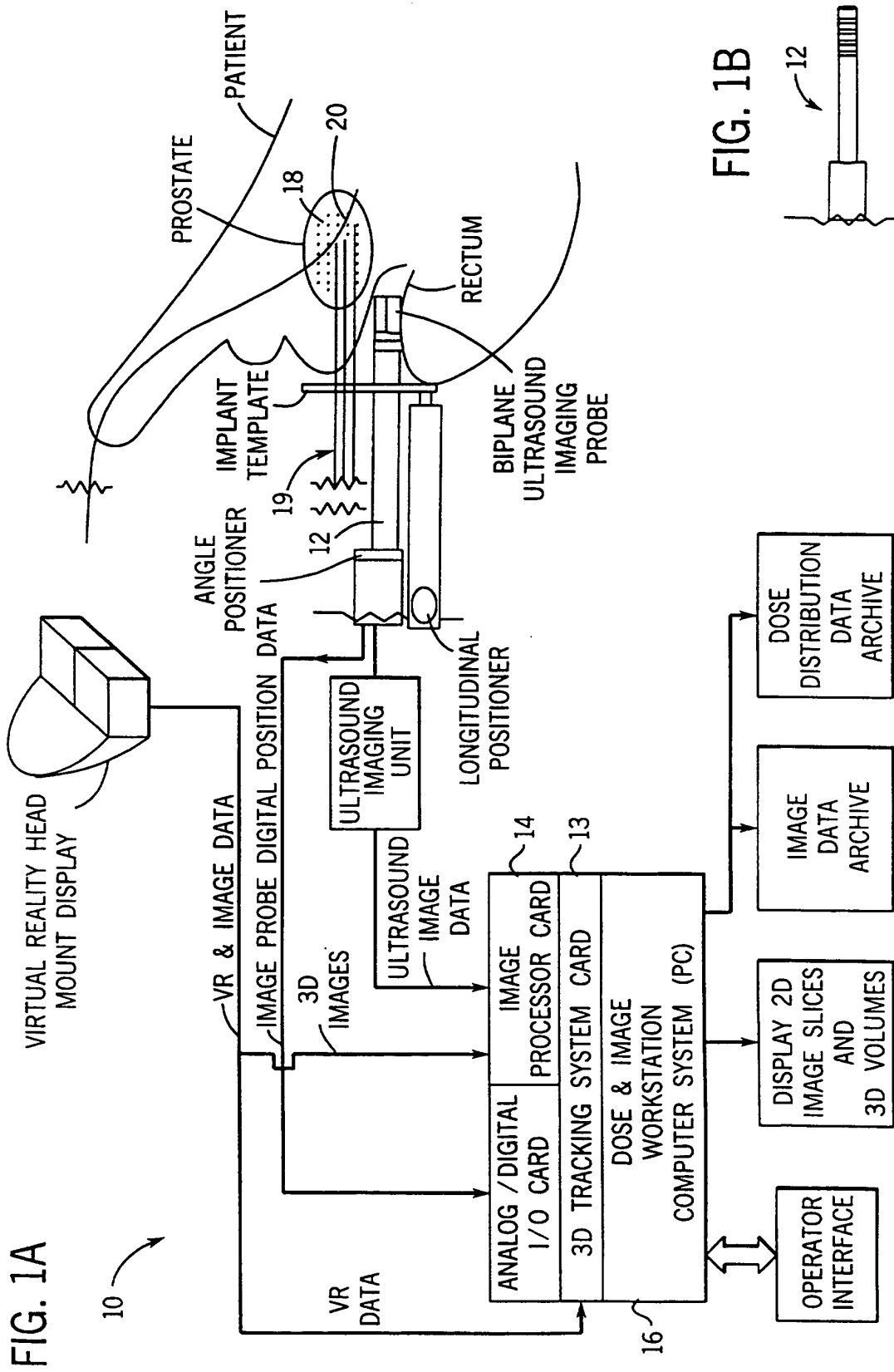
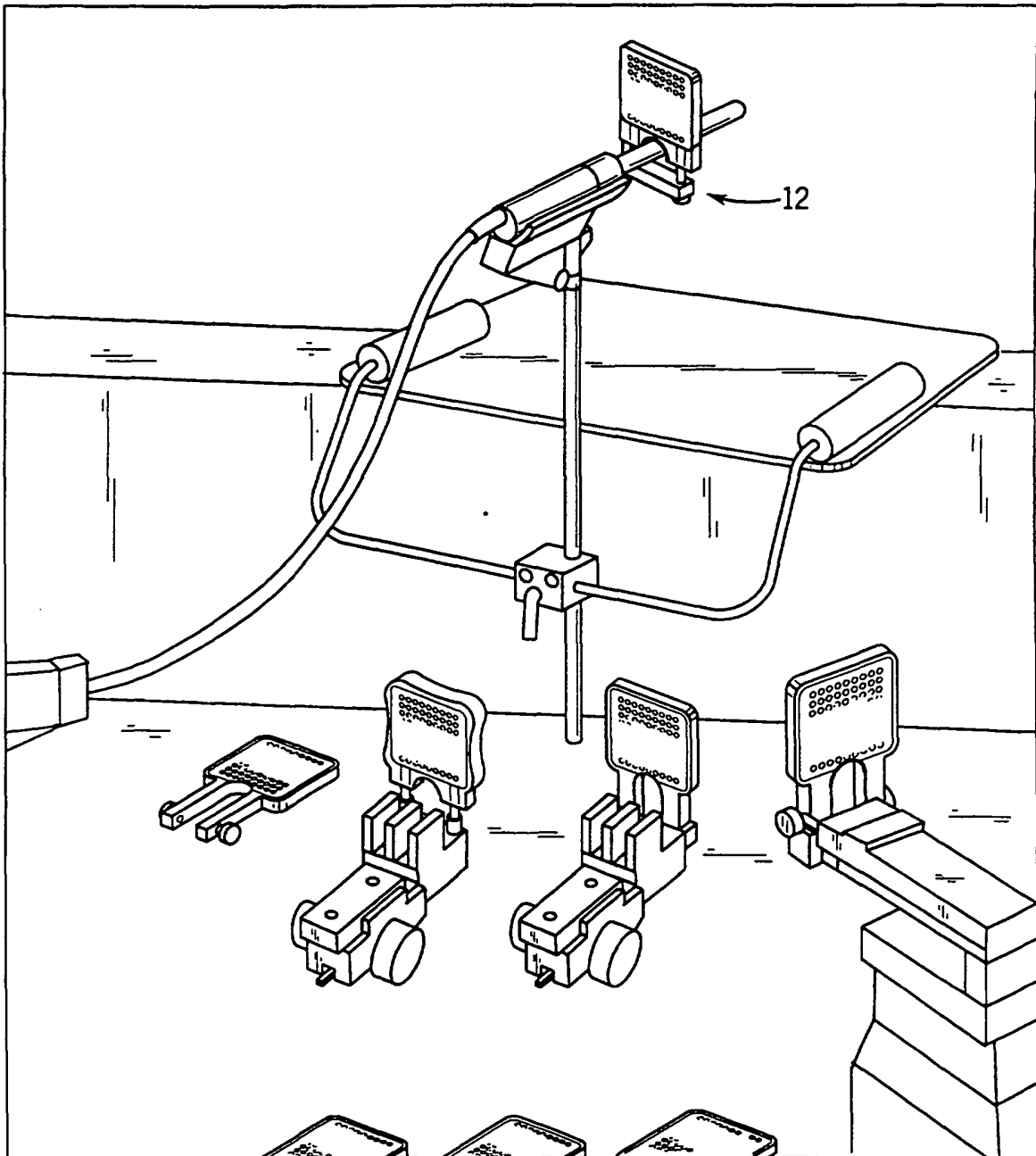


FIG. 2



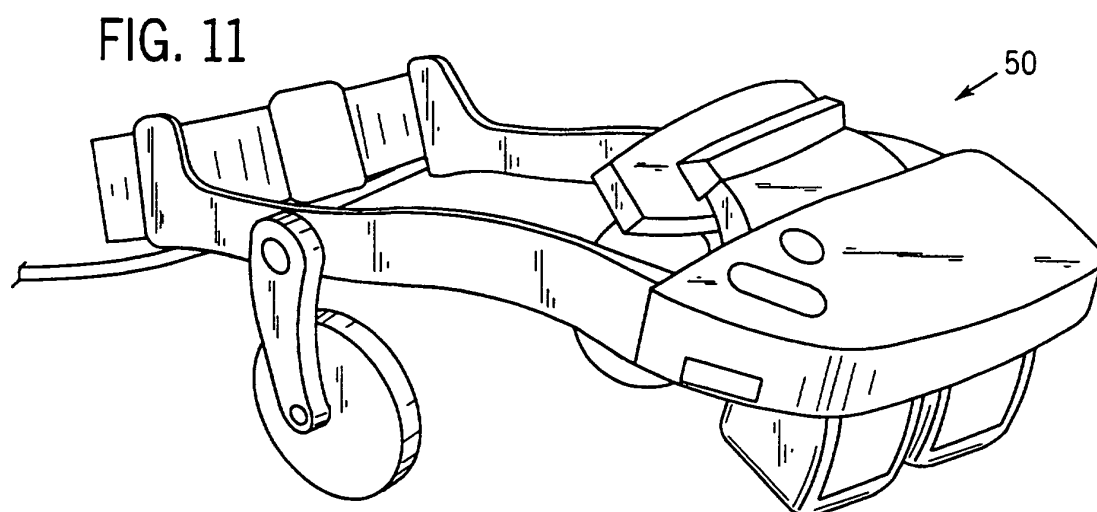
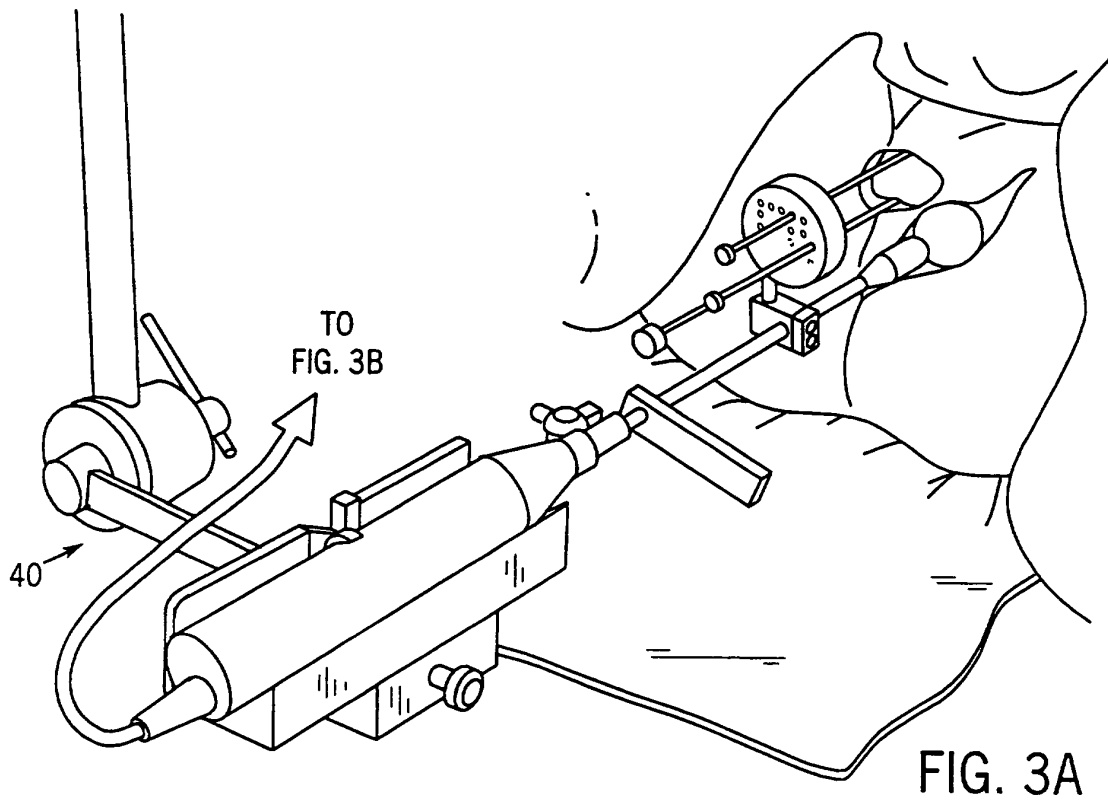




FIG. 3B

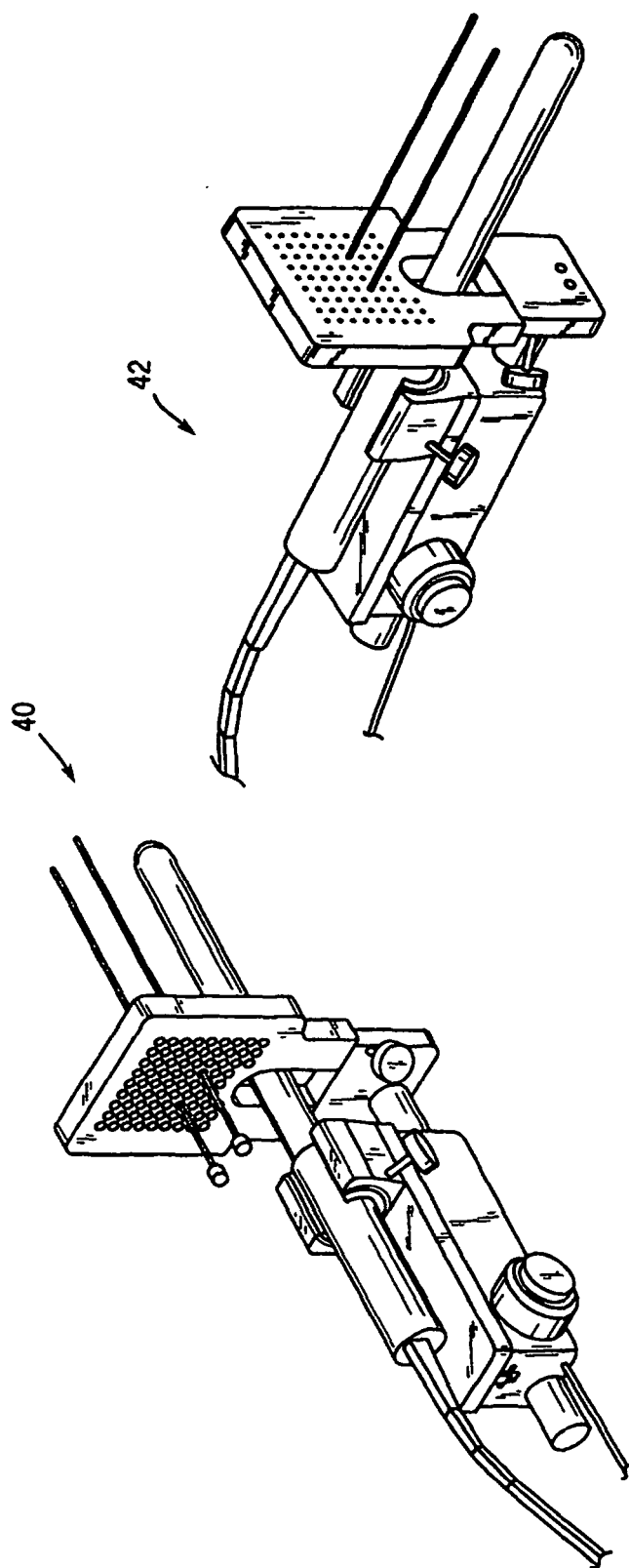


FIG. 3C

FIG. 4A

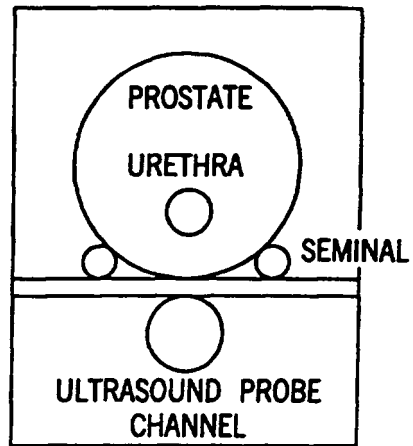


FIG. 4B

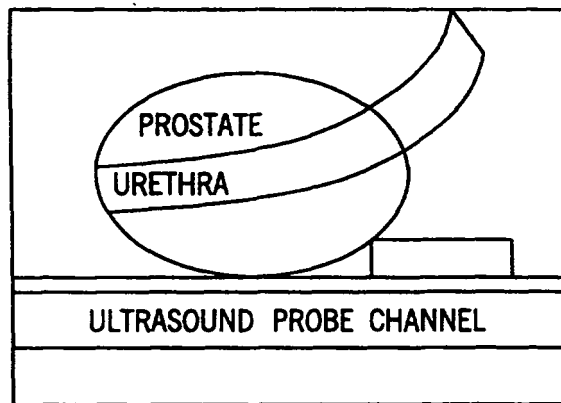
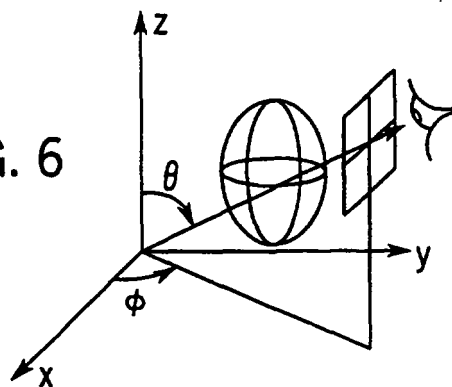


FIG. 6



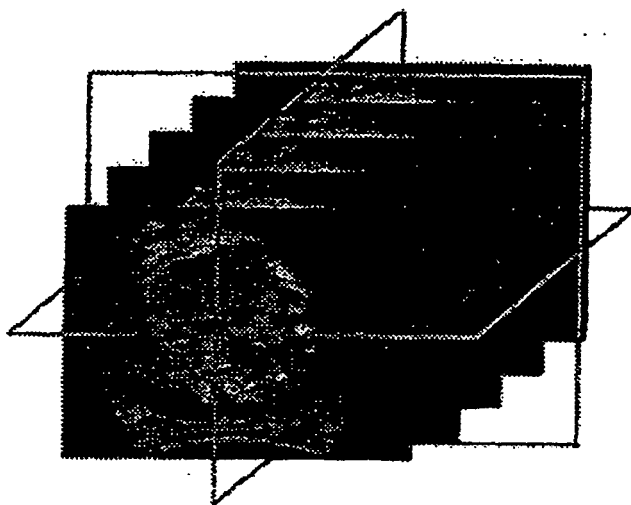


FIG. 5A

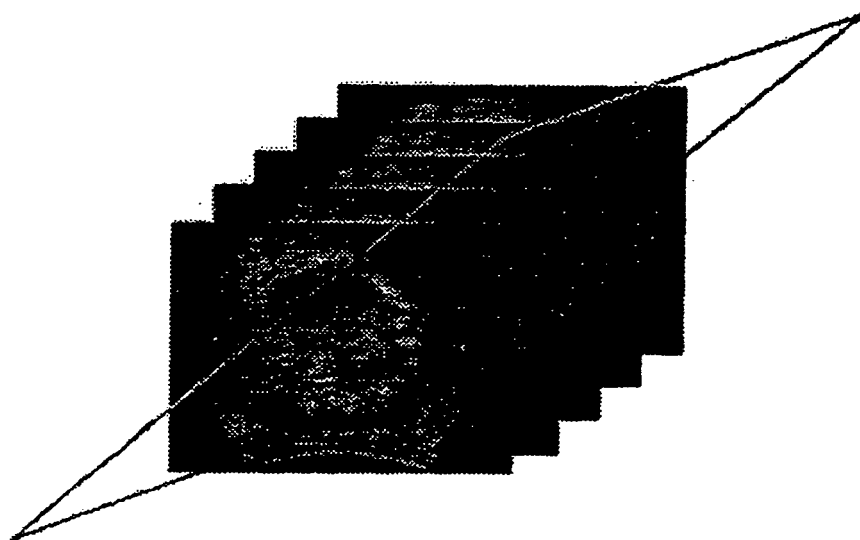


FIG. 5B

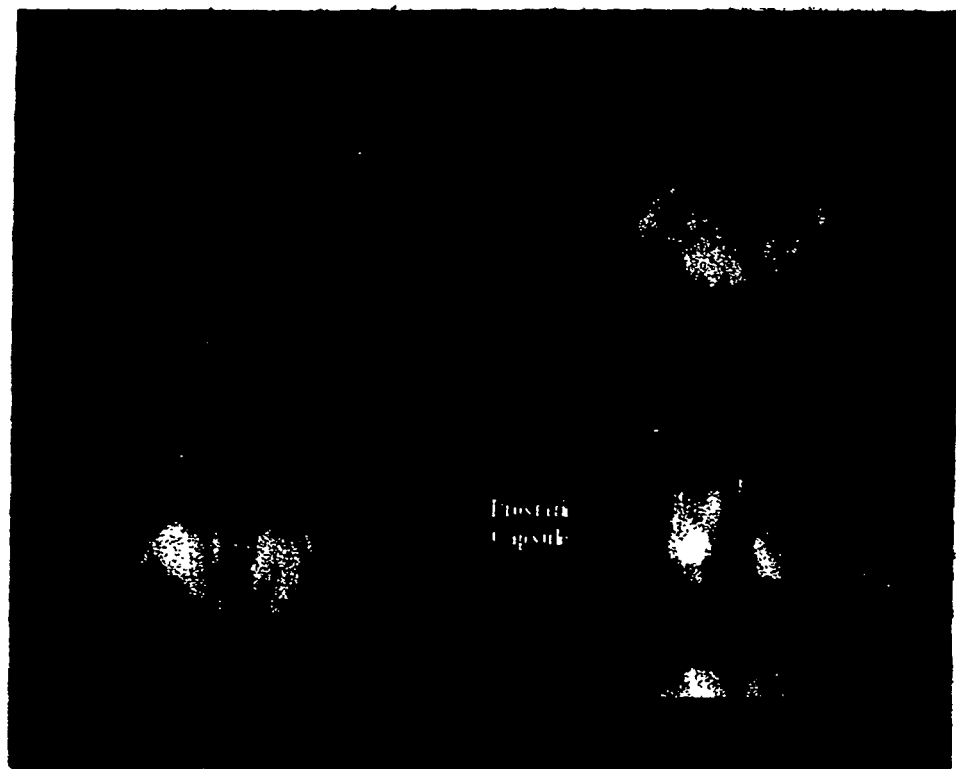


FIG. 7A

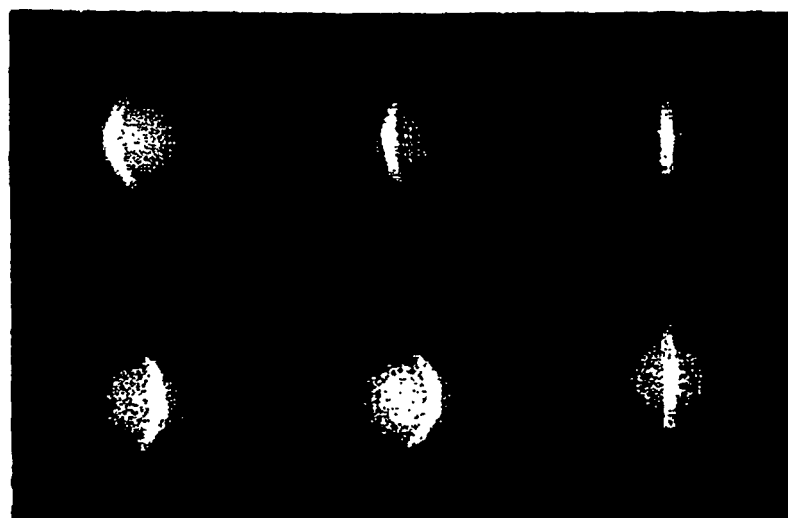


FIG. 7B

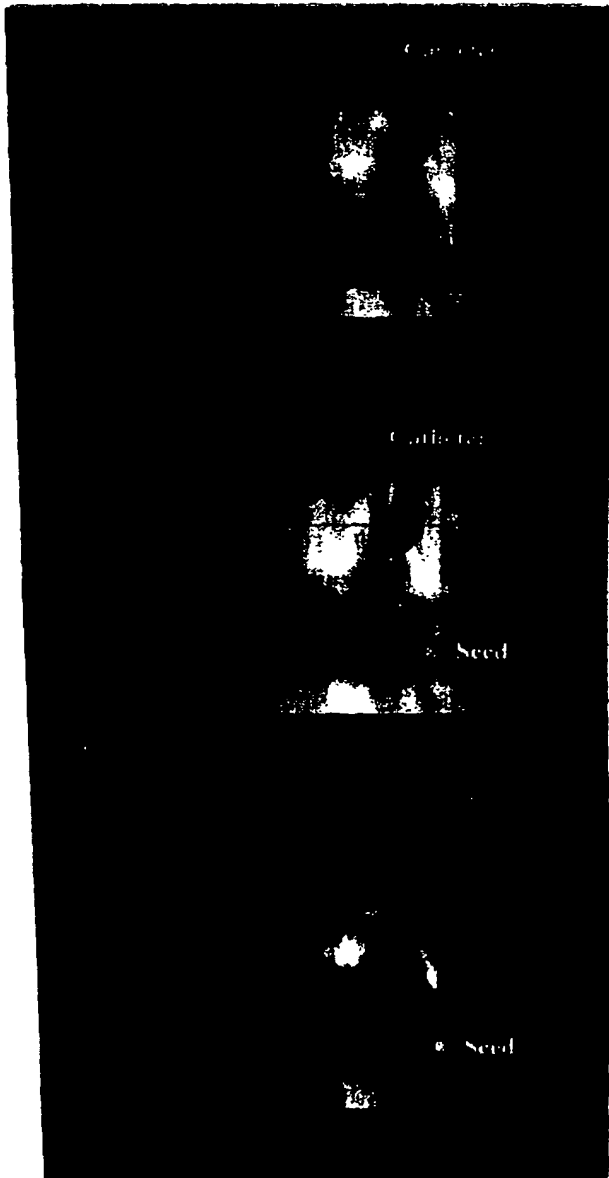
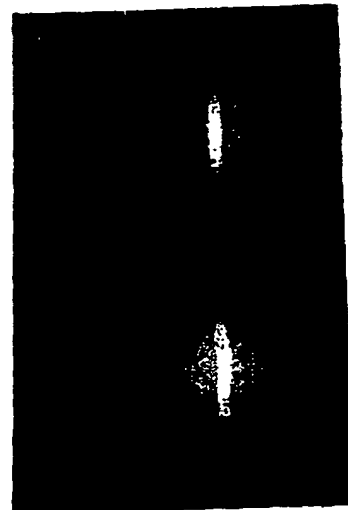


FIG. 8



3

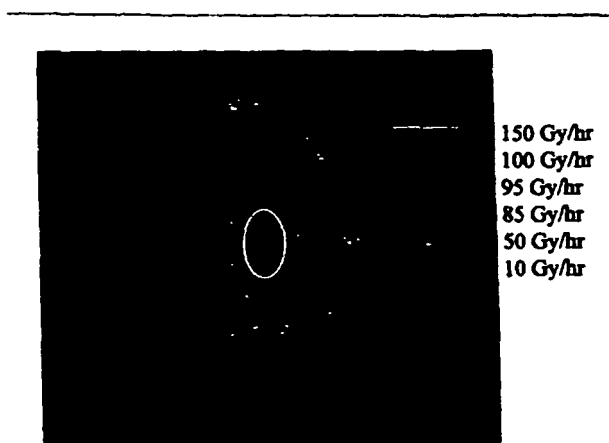
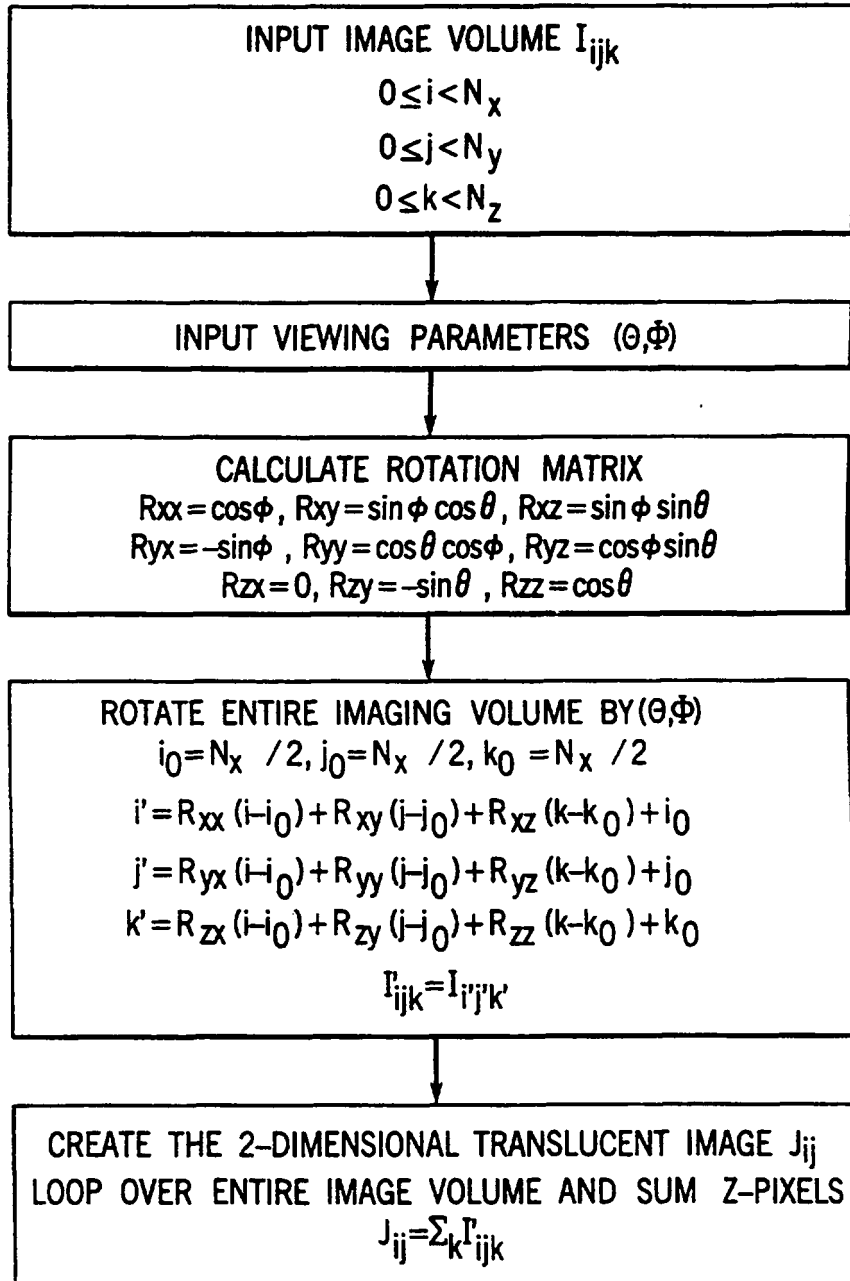


FIG. 9

FIG. 10



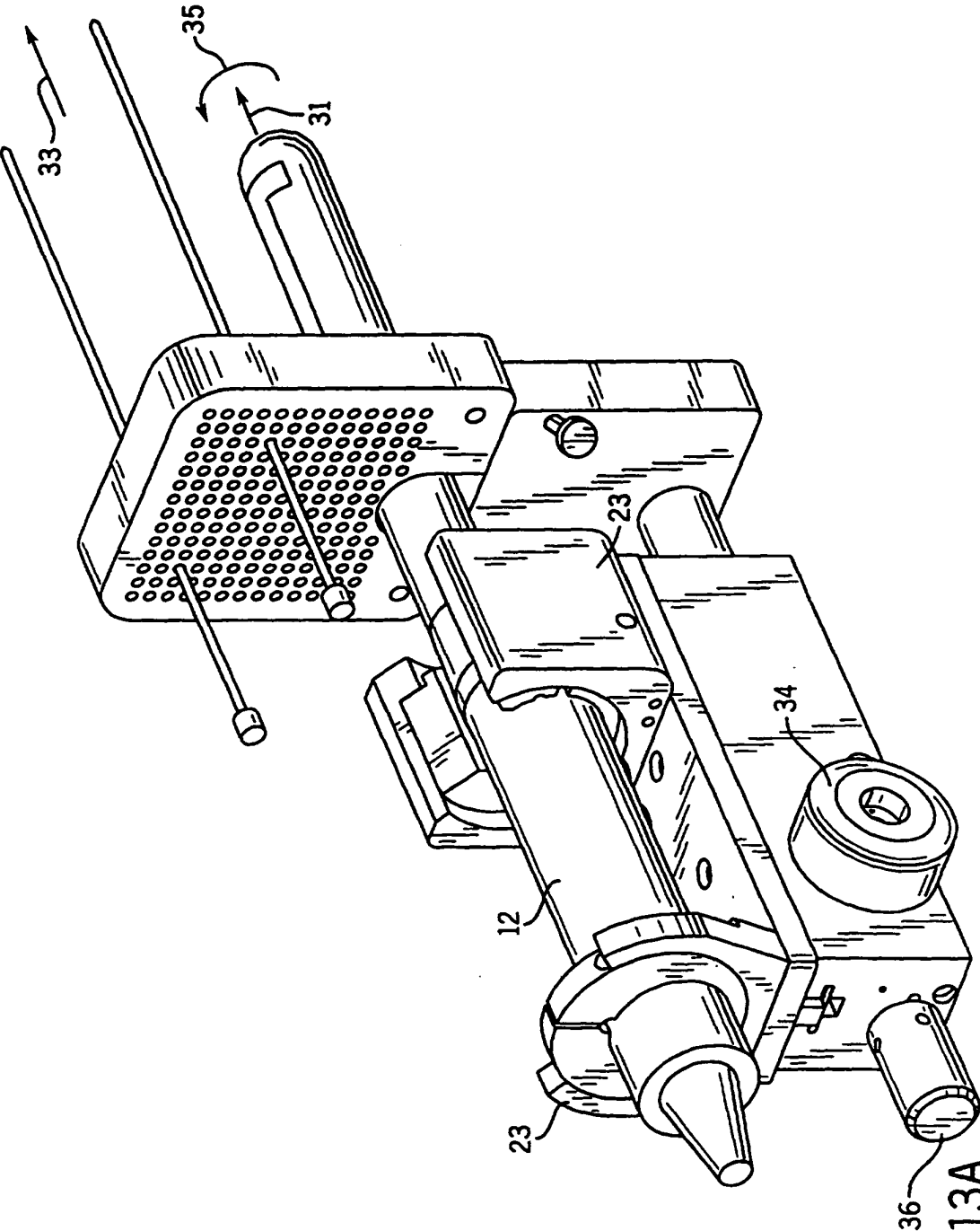


FIG. 13A

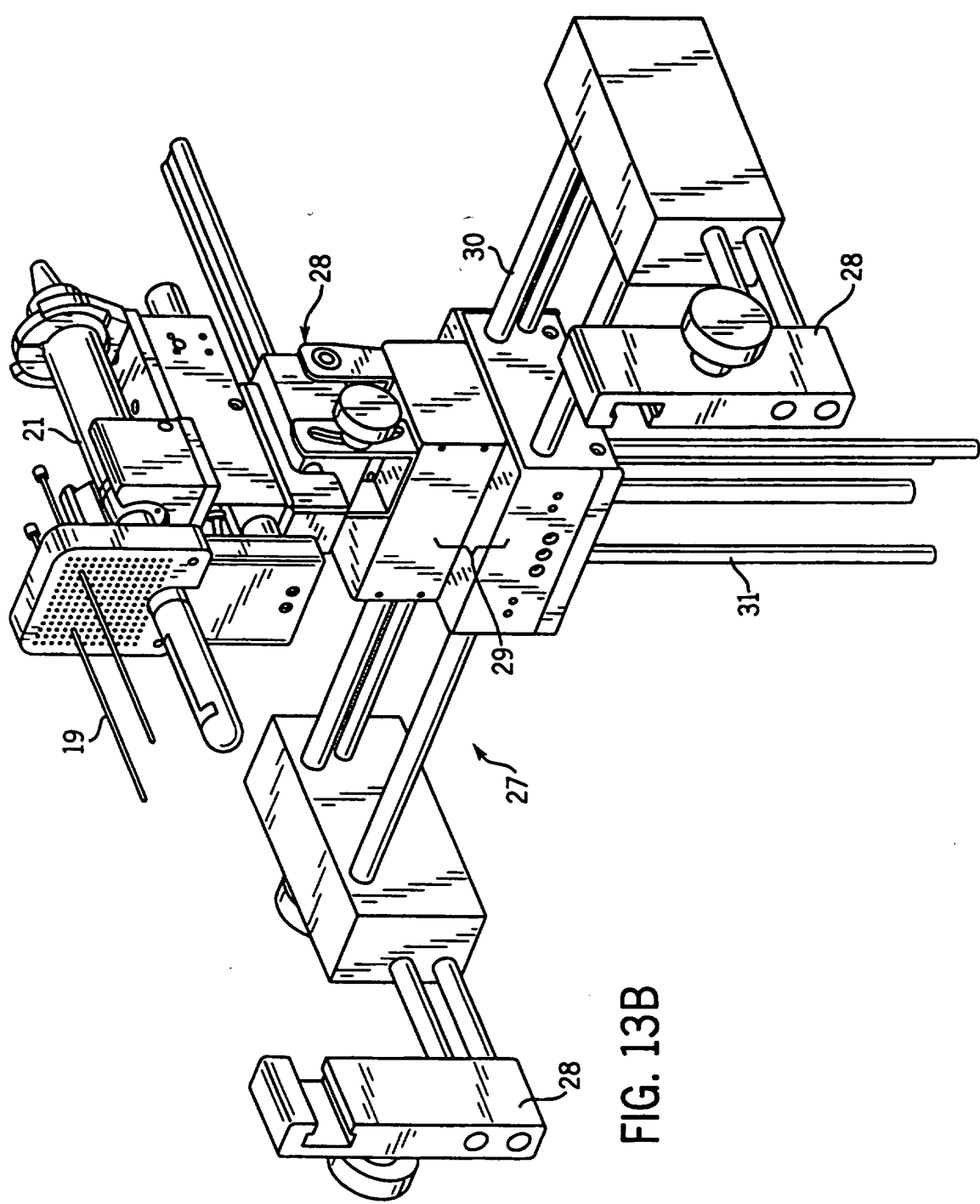


FIG. 13B

FIG. 14

